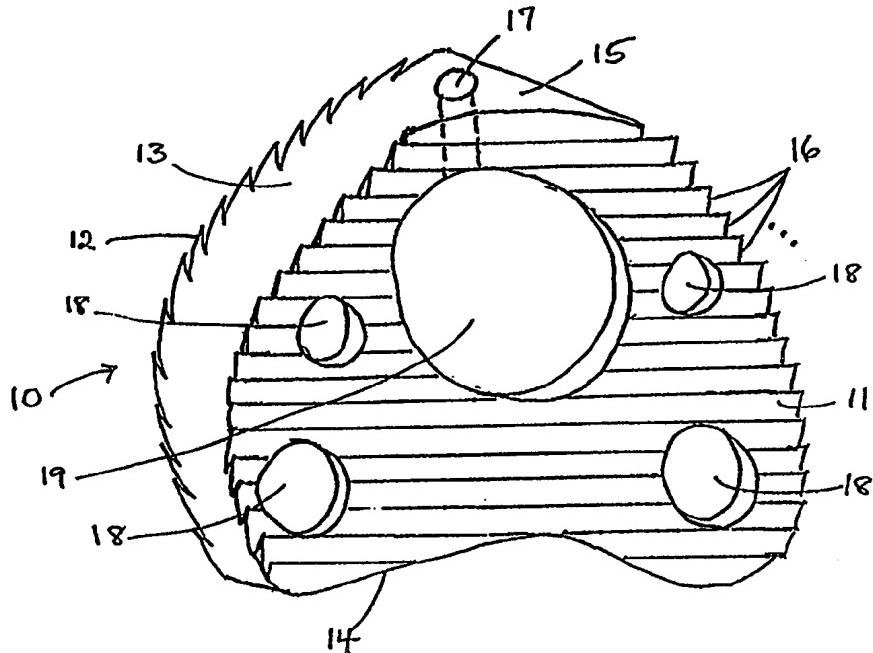




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(54) Title: RESORBABLE INTERBODY SPINAL FUSION DEVICES



## (57) Abstract

A resorbable interbody fusion device (10) for use in spinal fixation is disclosed. The device (10) is composed of 25 % to 100 % bio-resorbing or resorbing material. A preferred resorbable spinal fusion device (10) is in the shape of a tapered wedge having a top face (11), a bottom face (12), side faces (13), a front end (14), and a back end (15). The surfaces of the top (11), and bottom (12) faces each have serration (16) to aid in anchoring the device (10) to the surrounding bone. The fusion device (10) preferably has holes (17) of convenient diameter to facilitate resorption of the polymer from which the device has been made.

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## TITLE OF THE INVENTION

Resorbable Interbody Spinal Fusion Devices

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## CROSS REFERENCE TO RELATED APPLICATIONS

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This application claims priority from U.S. Provisional Patent Application Nos. 60/055,291, filed August 13, 1997; 60/074,076, filed February 9, 1998; 60/074,197, filed February 10, 1998, and 60/081,803, filed April 15, 1998, the entire disclosures of which are incorporated herein by reference.

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## STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

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Not applicable

## BACKGROUND OF THE INVENTION

The present invention relates to the field of interbody spinal fusion devices.

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In the structure of the spine of vertebrates including humans, the space between adjacent vertebrae is referred to as the interbody space. In normal spines, this space is occupied by the structure commonly referred to as a disc. This intervertebral structure separates and cushions the vertebrae.

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Various pathologic and traumatic conditions require excision of a spinal disc and stabilization of the superior and inferior vertebrae while bony fusion develops. In 1995, approximately 225,000 new spinal fusions were performed in the United States alone, and of these about one half were performed in the thoracic and cervical spine, with the remaining spinal fusions focused on the lumbar spine. To stabilize the spine where the surgery has occurred, an internal fixation device is frequently used. Such implants provide the ability to improve spinal alignment and maintain the developing alignment while fusion develops. Fixation of the spine can further correct deformity and provide immediate stability, thereby facilitating spinal fusion, early

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mobilization, and, when necessary, entry into rehabilitative programs.

The use of fixation devices is beneficial in several ways. First, the avoidance of long-term bed rest, thought by many to decrease non-neurological morbidity, is achieved. Additionally, fixation devices are thought to promote fracture healing and therefore reduce the need for rigid and cumbersome post-operative bracing.

While a number of commercially available implants for spinal stabilization are known, these devices are not resorbable and therefore, remain permanently at the implant site. Meticulous bone preparation and grafting is essential for successful long-term stability using current devices. Metallic and graphite implants have been known to fatigue and will eventually fail if the desired solid bony fusion is not achieved. Thus, it would be advantageous to obtain successful bony fusion and spinal development while avoiding the use of devices having the aforementioned drawbacks.

#### SUMMARY OF THE INVENTION

The present invention is directed to resorbable interbody fusion devices for use as spacers in spinal fixation, wherein the device is composed of 25-100% bioresorbable or resorbable material. The devices can be in any convenient form, such as a wedge, screw or cage. In one embodiment, the interbody fusion device of the invention further desirably incorporates structural features such as serrations to better anchor the device in the adjoining vertebrae. In another embodiment, the device comprises a plurality of peripheral voids and more desirably a central void space therein, which may desirably be filled with a grafting material for facilitating bony development and/or spinal fusion, such as an autologous grafting material. In addition, void spaces increase the surface area of the device, thereby providing multiple sites for resorption to occur.

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In yet another embodiment, the interbody fusion device of the invention further includes reinforcing fibers to enhance the structural properties thereof. These fibers may be made of the same polymeric material as the resorbable material from which the interbody fusion device is made, from a neutralization compound or, alternatively, from another biocompatible polymer, which may be crosslinked with a suitable crosslinking agent to yield an interpenetrating network for increased strength and stability. In another alternative embodiment, the reinforcing fibers are incorporated into the device, e.g., during the molding process, being placed in the mold under tension and released after the process of molding is complete.

Bioerodible polymers that are useful in the invention include polydioxanone, poly( $\epsilon$ -caprolactone); polyanhydride; poly(ortho ester); copoly(ether-ester); polyamide; polylactone; poly(propylene fumarate) ( $H[-O-CH(CH_3)-CH_2-O-CO-CH=CH-CO-]_nOH$ ); and combinations thereof. In a preferred embodiment, the polymer poly(lactide-co-glycolide) (PLGA:  $H[-OCHR-CO-]_nOH$ , R=H, CH<sub>3</sub>), with a lactide to glycolide ratio in the range of 0:100% to 100:0% inclusive, is used.

As many of the preferred bioerodible polymers from which the resorbable interbody fusion device is manufactured are polymers that can produce acidic products upon hydrolytic degradation, the device preferably further includes a neutralization compound, or buffer. The neutralization compound is included in sufficiently high concentration to decrease the rate of pH change as the device degrades, in order to prevent sterile abscess formation caused by the accumulation of unbuffered acidic products in the area of the implant. Most preferably, the buffering or neutralizing agent is selected from a group of compounds wherein the pKa of the conjugate acids of the buffering or neutralization compound is greater than the pKa of the acids produced by hydrolysis of the polymers from which the device is prepared.

The neutralization compound, or buffer, included in the bioerodible material of the invention may be any base, base-

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containing material or base-generating material that is capable of reacting with the acidic products generated upon hydrolysis of the bioerodible polymer. Polymeric buffers which preferably include basic groups which neutralize the acidic degradation products may also be used as buffering compounds. Another class of useful buffering compounds are those which, on exposure to water, hydrolyze to form a base as one reaction product.

In another alternative embodiment, the resorbable interbody fusion device of the invention preferably includes a biological growth factor, e.g., bone morphogenic protein, to enhance bone cell growth. To protect the growth factor and to provide for controlled delivery, the biological growth factor may itself be compounded with a resorbable polymer in some of the many techniques available and prepared as a growth factor/polymer composite in pellet form, in small particle form or within the interstices or pores of a polymeric foam or low-density polymer and this polymer/growth factor composite is deposited into void spaces of the resorbable spinal fusion device. Alternatively, the growth factor, or protected growth factor, may simply be directly incorporated into the component formulation of the resorbable spinal fusion device.

Active periosteum cells may also be incorporated into a foam, e.g., deposited into void spaces of the resorbable spinal fusion device, in order to facilitate bone cell fusion. Further, the resorbable spinal fusion device of the invention may be prepared in such a manner as to exhibit a piezoelectric effect, to enhance bone wound healing.

As used herein, the terms "resorbable" and "bioresorbable" are defined as the biologic elimination of the products of degradation by metabolism and/or excretion and the term "bioerodible" is defined as the susceptibility of a biomaterial to degradation over time, usually months. The terms "neutralization compound" or "buffer" are defined as any material that limits or moderates the rate of change of the pH in the implant and its near environment upon

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exposure to acid or base. The term "acidic products" is defined herein as any product that generates an aqueous solution with a pH less than 7.

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#### DESCRIPTION OF THE DRAWINGS

The invention will be more fully understood from the following detailed description taken in conjunction with the accompanying drawings in which:

10 Figs. 1A, 1B and 1C are perspective top, side and front views, respectively, of an interbody spinal fusion device according to the present invention;

15 Figs. 2A, 2B and 2C are top, side and perspective views, respectively, of another embodiment of an interbody spinal fusion device of the invention;

20 Figs. 3A, 3B and 3C are top, side and perspective views, respectively, of another embodiment of an interbody spinal fusion device of the invention;

25 Figs. 4A and 4B are side and top views, respectively, of another embodiment of an interbody spinal fusion device of the invention;

30 Figs. 5A and 5B are side and top views, respectively, of another embodiment of an interbody spinal fusion device of the invention;

Fig. 6A is a perspective view of a mold and ram assembly for preparing an interbody spinal fusion device of the invention;

35 Figs. 6B and 6C are edge and plan views, respectively, of the front face plate of the mold of Fig. 6A;

Fig. 6D shows a disc with serrated slots for use in the mold of Fig. 6A;

Figs. 6E and 6F are front and side views, respectively, of a threaded tension tube used with the mold of Fig. 6A;

Fig. 6G is a section through a mold assembly fitted with reinforcing fibers and associated holder assemblies;

35 Fig. 7 is a plot of displacement versus load for an interbody spinal fusion device of the invention; and

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Fig. 8 shows compression strength with load, for interbody spinal fusion devices of the invention with and without the incorporation of a buffering or neutralizing compound.

5

#### DETAILED DESCRIPTION OF THE INVENTION

The present invention provides, in one embodiment, an interbody spinal fusion device (IFD) comprising a resorbable spinal wedge for vertebral spacing as an adjunct to spinal fusion. Made from a biodegradable, biocompatible polymer, preferably poly(lactic-co-glycolic) acid (PLGA), discussed further below, this resorbable spacer incorporates peripheral voids and central voids, which can be filled with autologous grafting material to facilitate bony development and spinal fusion, and serrated or threaded faces to stabilize and align vertebral bodies. The spinal fusion device of the invention is used as an adjunct to fusions of the cervical, thoracic or lumbar vertebrae, the configuration and dimensions of the device depending on the site of use.

A preferred embodiment of a spinal implant, fabricated from a biocompatible and biodegradable polyester and intended to replace a cervical disc, C4, 5, or 6, is shown in Figs. 1A, 1B and 1C. A rod molded from a suitable material, as described below, is machined to the desired configuration and dimensions. Relatively complex geometries can be readily fabricated in this manner. Suitable biocompatible extraneous materials such as plasticizers or other machining aids, can be included in the material if desired.

As shown in Fig. 1A, a preferred resorbable interbody spinal fusion device of the invention 10 is in the shape of a tapered wedge, having a top face 11, a bottom face 12, side faces 13, a front end 14 and a back end 15. The surfaces of top and bottom faces 11 and 12 each have serrations 16 to aid in anchoring the device to the surrounding bone. Wedge 10 preferably contains holes 17 of convenient diameter, which may be drilled through the wedge to facilitate resorption of the polymer from which the device has been made. A plurality

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of channels or ports 18 through the wedge or a larger center hole 19 in the wedge are useful for the introduction of autologous bone. As illustrated in Figs. 1B and 1C, the spinal wedge is preferably machined to have a taper from back end 15 to front end 14, such that the front end 14 is narrower than the back end 15.

In another embodiment, as shown in Figs. 2A-2C resorbable spinal fusion device 20 is shaped like a tapered rod having ridges 22 with threads 21. Device 20 functions as a screw and contains a cylindrical axially extending hole 23 and slots 24 to facilitate screwing the device into the spine of the patient. The device also contains recesses 26 between ridges 22 to facilitate ingrowth of tissue that would aid in anchoring the device in place.

As shown in Figs. 3A-3C, in a further embodiment, the device 30 is of cruciform shape having arms 33. Threads 31 extend the length of the outer surfaces of arms 33. In another embodiment, shown in Figs. 4A-4B, the device is shaped like a threaded screw having a continuous thread 41 provided around the surface of the tapered body. Cylindrical holes 43 and 44 are provided through the body, the holes being orthogonal to each other and to screw axis 42. A cylindrical hole 45 is provided coaxially with axis 42. Slots 46 in the top 48 serve to position and retain a tool that can be used to screw the device into place.

As shown in Figs. 5A and 5B, a further embodiment of a threaded screw contains flat side areas 52 alternating with threaded corner areas 51. Slots 53 can be machined or otherwise provided in the flat areas, to facilitate ingrowth of tissue, and can be of a constant width or can be tapered. A slot 56 in top 58 of the device accommodates a suitable tool to facilitate insertion.

For replacement of one of the cervical discs C4, C5, or C6, the device shown in Figs. 1A-1C preferably measures 15 mm laterally by 12 mm sagittally. The flattened side, positioned posterioly, is 6-8 mm thick, enlarging to about 7-9 mm at the anterior edge; thus the device has a taper of

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approximately 4.8 degrees. Both surfaces are serrated, the serrations directed laterally. The serrations may be either square cut or cut at an angle with one face vertical and the other sloping upward anteriorly.

5       The thickness of the device of the invention will govern the rate at which it degrades and total degradation time. Thus, interbody spinal fusion devices can be prepared with multiple thicknesses, but all having the same approximately 10 5° taper. For example, the anterior thickness could range from 7 to 9 mm and the posterior thickness from 6 to 8 mm. The taper provides the correct orientation to the vertebrae with which the device is in contact and can also serve to keep the device in place.

15      The vertebral body is a fairly cylindrical mass consisting of cancellous bone surrounded by a thin layer of cortical bone. Thus, the mechanical properties of the device should preferably match those of the cancellous bone of the vertebrae in regard to proportional limit stress, compression at proportional limit, modulus of elasticity, failure stress 20 and compression at failure (See, e.g., Lindahl, Acta Orthop. Scand. 47:11, 1976; Hansson et al., Spine 12:56, 1987).

25      Bioerodible polymers that are useful in the spinal fusion device of the invention include polydioxanone, poly( $\epsilon$ -caprolactone); polyanhydride; poly(ortho ester); copoly(ether-ester); polyamide; polylactone; poly(propylene fumarate) ( $H[-O-CH(CH_3)-CH_2-O-CO-CH=CH-CO-]_nOH$ ); poly(lactic acid); poly(glycolic acid); poly(lactide-co-glycolide); and combinations thereof. Selection of a particular polymer is based primarily on the known properties of the polymer, such 30 as the potentiality for cross-linking, polymer strength and moduli, rate of hydrolytic degradation, etc. One of ordinary skill in the art may take these and/or other properties into account in selecting a particular polymer for a particular application. Thus, the selection of a particular polymer is 35 within the skills of the ordinary skilled practitioner.

In a preferred embodiment, the polymer poly(lactide-co-glycolide) ( $H[-OCHR-CO-]_nOH$ , R=H, CH<sub>3</sub>) (PLGA) is used. The

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PLGA polymers used according to the invention desirably have a lactide to glycolide ratio in the range of 0:100% to 100:0%, inclusive, i.e., the PLGA polymer can consist of 100% L- or D,L-lactide (PLA), 100% glycolide (PGA), or any combination of lactide and glycolide residues. These polymers have the property of degrading hydrolytically *in vivo* to form organic acids (lactic acid and glycolic acid) which accumulate in the region surrounding the implant. These acids are metabolized and eventually excreted as carbon dioxide and water or enter the citric acid cycle.

The process by which alpha polyesters such as PLA, PGA, and PLGA biodegrade is primarily by non-specific hydrolytic scission of the ester bonds. The L-lactic acid that is generated when PLA or PLGA degrades becomes incorporated into the tricarboxylic acid cycle and is excreted from the lungs as carbon dioxide and water. Glycolic acid, produced both by random hydrolytic scission and by enzymatically mediated hydrolysis, may be excreted in the urine and also can enter the TCA cycle and eventually be oxidized to carbon dioxide and water (Hollinger et al., Clin. Orthop. Rel. Res. 207: 290-305, 1986).

A particularly preferred polymer for use in the device of the invention is poly(d,l-lactide-co-glycolide)-85:15 (Boehringer-Ingelheim: distributor, Henley Chemicals, Inc., Montvale, NJ), the 85:15 designation referring to the lactide to glycolide mole ratio. The particularly preferred polymer is Resomer™ RG 858, with an inherent viscosity of approximately 1.4 corresponding to a weight average molecular weight of 232,000 as measured by gel permeation chromatography (GPC).

The polymer can be used as received or purified by precipitation from tetrahydrofuran solution into isopropanol, air dried and then exhaustively vacuum dried. Polymer data (composition and molecular weight) can be confirmed by nuclear magnetic resonance and by GPC (Hsu et al., J. Biomed. Mater. Res. 35:107-116, 1997).

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Spinal fusions require interbody fusion devices that will maintain significant structural rigidity for 6-12 months. Strength requirements depend on the location of the disc to be replaced. When a person is standing, the forces to which a disc is subjected are much greater than the weight of the portion of the body above it. Nachemson et al. (Acta Orthop. Scand. 37:177, 1966; J. Bone Joint Surgery 46:1077, 1964; Clin. Orthop. 45:107, 1966) has determined that the force on a lumbar disc in a sitting position is more than three times the weight of the trunk. Daniels et al. (J. Appl. Biomater. 1:57-78, 1990) have reviewed much of the mechanical data of PGA, PLA, and PLGA.

As a bioerodible polymer undergoes hydrolysis in the body, any acidic degradation products formed may be implicated in irritation, inflammation, and swelling (sterile abscess formation) in the treated area. To counteract this effect, a neutralization compound, or buffer, is desirably included in the bioerodible material to neutralize the acidic degradation products and thereby reduce the sterile abscess reaction, as described in copending U.S. Application No. 08/626,521, filed April 3, 1996, the whole of which is hereby incorporated by reference herein.

The buffering compound included in the bioerodible material of the invention may be any base, base-containing or base-generating material that is capable of reacting with the acidic products generated upon hydrolysis of the bioerodible polymer. Exemplary buffering materials include salts of inorganic or organic acids, salts of polymeric organic acids or polymeric bases such as polyamines. Preferably calcium salts of weak acids such as, e.g., tribasic calcium phosphate, dibasic calcium phosphate, or calcium carbonate are used. To be useful, the conjugate acids from which the buffering materials are derived must have a pKa greater than those of L-lactic acid (pKa = 3.79), D, L-lactic acid (pKa = 3.86), or glycolic acid (pKa = 3.83), if a PLGA is the polymer which is undergoing hydrolysis. Thus,

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for example, salts of acetic acid ( $pK_a = 4.74$ ), or succinic acid ( $pK_1 = 4.19$ ,  $pK_2 = 5.64$ ) may also be used.

Buffer compositions of lower solubility are preferred because buffer loss from the polymer by diffusion will be slower (Gresser and Sanderson, "Basis for Design of biodegradable Polymers for Sustained Release of Biologically Active Agents" in Biopolymeric Controlled Release Systems, Ch. 8, D.L. Wise, Ed., CRC Press, 1984). Preferably, the buffering compound has an acid dissociation constant that is smaller than the acid dissociation constant of the acidic products generated upon hydrolysis of the bioerodible polymer. Ionic buffers will, in general, be the salts of weak acids. The acid, of which the buffer is a salt, should have an ionization constant (acid dissociation constant,  $K_a$ ) which is less than the  $K_a$  for the acid products of polymer hydrolysis. Alternatively, the buffering compound has a hydrolysis constant that is greater than the hydrolysis constant of the acidic products.

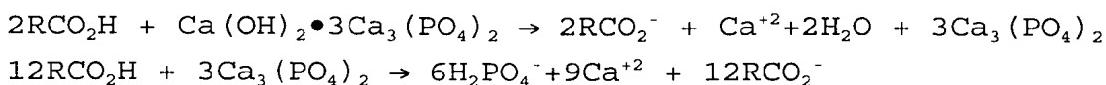
Hydroxyapatite (HA) and calcium carbonate (CC) were each investigated as buffering fillers. Results demonstrate that the inclusion of CC or HA in a, e.g., PLGA fixture can effectively moderate the rate of pH decline as the fixture degrades. Further, the rapid decline in pH can be offset without considering 100% neutralization of the lactic and glycolic components. Thus, even given that the polymeric fixture will be filled with an inorganic buffer, the mechanical characteristics of the fixture can be stabilized since the loading requirements for the buffer will not be nearly as compromising as expected at the outset.

While both CC and HA can ameliorate the rate of decline in pH in the region of polymer hydrolysis, the use of hydroxyapatite as a filler also supports osteoconductivity. Thus, HA not only promotes bony ingrowth and obviates loosening of the fixture, but also acts as a buffer thereby preventing the formation of sterile abscesses that have been attributed to the acidic degradative products of PLGA implants. The resulting resorbable fixture should be capable

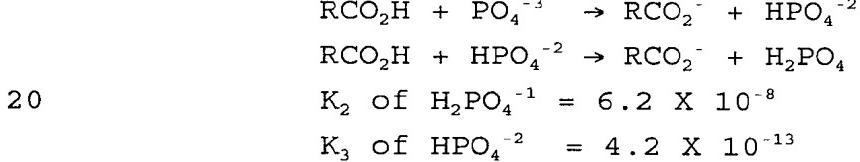
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of a buffered hydrolytic degradation and induction of bony ingrowth as resorption of the implant progresses. A resorbable buffered bone fixture with such properties could provide structural support to stabilize and support a spinal repair over the period of time required for natural healing to occur.

According to the invention a preferred buffering compound is hydroxyapatite. The formula  $\text{Ca}_{10}(\text{OH})_2(\text{PO}_4)_6$  may be written as  $\text{Ca}(\text{OH})_2 \bullet 3\text{Ca}_3(\text{PO}_4)_2$ . When written in this manner it is seen that the following neutralization reactions may be written:



The dissociation constant of water (the conjugate acid of the hydroxyl ion) is  $K_w = 10^{-14}$ . The basic phosphate ion,  $\text{PO}_4^{-3}$ , can neutralize two protons forming the following acids, for which dissociation constants are given:



Buffers included in the polymer in solid form preferably have a relatively small particle size, for example, between less than 1.0 and 250  $\mu\text{m}$ . Particle size reduction can be accomplished by any standard means known in the art, such as ball milling, hammer milling, air milling, etc. If buffer and polymer are to be blended by the dry mixing method (described below), the polymer particle size must also be considered. Polymers such as the PLGAs have relatively low glass transition temperatures and melting temperatures. Thus, polymer particle size reduction must be accompanied by cooling, for example using a Tekmar A-10 mill with a cryogenic attachment.

Following milling, the desired particle size range of the buffer and the polymer may be recovered by sieving through, for example, U.S. Standard sieves. Particles in the

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size ranges of <45, 45-90, 90-125, 125-180, 180-250  $\mu\text{m}$  may be conveniently isolated.

In selection of particle size range, it is sometimes desirable to combine two or more ranges, or to use a wide range of sizes, for instance all sizes less than 250  $\mu\text{m}$ .  
5 Larger particles may be preferred in some applications of the invention because larger particles take longer to be eroded by the acids and will therefore extend the useful lifetime of the buffer. In some cases particle size reduction will  
10 not be necessary, such as when commercially available precipitated calcium carbonate is used (e.g., Fisher Scientific, Inc., Catalog No. C-63).

The effectiveness of substances such as calcium carbonate and hydroxyapatite in neutralizing the acid products of polymer hydrolysis depends not only on the quantity of the substance in the matrix, but also on particle size and distribution, total surface area in contact with the polymer, and solubility.  
15

The presence of calcium ions in the buffered device has advantages with respect to the physical properties of the device as it undergoes erosion. It has been shown that calcium ions form ionic bridges between carboxylate terminal polymer chains (Domb et al., J. Polymer Sci. A28, 973-985  
20 (1990); U.S. Pat. No. 4,888,413 to Domb). Calcium ion bridges between carboxylate anions increase the strength of the composite in which the polymer chains are terminated by carboxylate anion end groups over similar chains terminated by the hydroxyl groups of, e.g., terminal glycol moieties or terminal  $\alpha$ -hydroxy acids. In an analogous manner, the  
25 polyesters comprising the family of PLGA's are expected to be strengthened by calcium bridges between carboxylate anion terminated chains. As shown in Fig. 8 PLGA-85:15 wedges reinforced with 40% HA showed an increase in compressive strength of approximately 5% over the nonreinforced controls.  
30

35 Another class of useful buffering compounds are those which, on exposure to water, hydrolyze to form a base as one reaction product. The generated base is free to neutralize

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the acidic products produced upon hydrolysis of the bioerodible polymer. Compounds of this type include aryl or alkyl carbamic acids and imines. These "base-generating compounds" offer the advantage that the rate of hydrolysis of the base generator may be selected to correlate to the rate of hydrolysis of the bioerodible polymer.

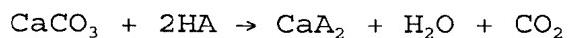
Necessarily, the conjugate acid of the buffering compound has an acid dissociation constant that is smaller than the acid dissociation constant of the acidic products generated upon hydrolysis of the bioerodible polymer. Alternatively, the buffering compound preferably has a hydrolysis constant that is greater than the hydrolysis constant of the acidic products.

Furthermore, the buffering compound preferably is only partially soluble in an aqueous medium. In general, buffers of lower solubility are preferred because buffer loss from the polymer by diffusion will be minimized (Gresser and Sanderson, *supra*). The quantity of buffer to include depends on the extent of neutralization desired. This may be calculated as shown below, using a PLGA of any composition buffered with calcium carbonate as an example.

The average residue molecular weight, RMW, for a PLGA is given by

$$\text{RMW} = 14.03x + 58.04$$

where  $x$  = mole fraction of lactide in the PLGA. The term "residue" refers to the repeating lactide or glycolide moiety of the polymer. For example, if  $x = 0.85$  (PLGA=85:15), RMW = 69.96. Thus, 1.0 gram of PLGA=85:15 contains 0.01429 moles of residues which, on hydrolysis of the polymer, will yield 0.01429 moles of lactic and/or glycolic acid. If, e.g., calcium carbonate is the buffering agent, and it is desired to neutralize, e.g., 50 mole % of the acids by the reaction



where A = lactate or glycolate, then the weight of calcium carbonate needed is  $(0.25)(0.01429)(100.09) = 0.358$  gram, and the required loading is  $(0.358)(1 + 0.358)(100) = 26.3\%$  by weight.

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Several methods may be used to incorporate the buffer into the polymer. These methods include solution casting coupled with solvent evaporation, dry mixing, incorporating the buffer into a polymer foam, and the polymer melt method.

5        Solution casting coupled with solvent evaporation may be used with buffers which are either soluble or insoluble in the solvent. The bioerodible polymer is dissolved in any suitable volatile solvent, such as acetone, tetrahydrofuran (THF), or methylene chloride. The buffer, which may be soluble or insoluble in this solvent, is added to give the final desired ratio of polymer to buffer. If particle size reduction of the buffer is necessary, it may be accomplished by ball milling the suspension of buffer in the polymer solution. In contrast, if the buffer is soluble in the chosen solvent, particle size reduction at any stage is not necessary.

10      The suspension or co-solution is cast as a film on a glass or other inert surface, and the solvent is removed by air drying. Residual solvent remaining in the film may be further removed by subjecting the film to vacuum drying at elevated temperatures. As an example, if calcium carbonate is to be used as a buffering compound and it is desired to neutralize 50% of the acid formed by hydrolysis of PLGA-20:50, the buffer content of the composition should be 27.8%.

15      25     In an exemplary embodiment, to prepare 50 grams of composite, 36.1 grams of PLGA-50:50 are dissolved in approximately 250 ml of tetrahydrofuran, and 13.9 grams of calcium carbonate of the desired particle size range is added to the solution mixture. After distributing the calcium carbonate homogeneously by mixing, the suspension is dried to a film as described above.

20      30     35    The resulting film may be processed by compaction under high pressure, extruded through a die, injection molded, or other method known in the art. Further definition of the final shape may be accomplished at this point by any desirable machining process, such as lathing.

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In the dry-mixing method, a polymer of appropriate particle size range is mixed with the buffer, also of chosen particle size range, in proportions to give the desired stoichiometric buffering capacity. The dry mixture is thoroughly blended by rotating the mixture in a ball mill jar from which the grinding balls have been omitted, or other suitable mixing device. The blended mixture may then be processed by compaction, extrusion, injection molding, etc., as described above.

In the polymer melt method, a known weight of the buffer is incorporated by mixing into a known weight of a suitable melted polymer. A quantity of polymer is heated to a temperature above its melting point, and a suitable buffer is blended into the melted polymer. The resulting polymer/buffer composite is solidified by cooling, and may be processed as described above, or ground and sieved prior to processing.

In some applications, it may be desirable to protect the buffering compound, for example, during processing according to the melt method, or to make the buffering compound available at the later stages of polymer degradation. In such cases, it is desirable to coat the buffering compound particles with a material that degrades at a slower rate than the material chosen for the fixation devices. Thus, the buffering compound is exposed only after the body of the device and the coating material have partially degraded. Exemplary materials used to coat the buffering compound particles include high molecular weight poly(L-lactide) or poly( $\epsilon$ -caprolactone).

The particles of buffering compound may be coated with the protective material by any method that coats particles, such as spray coating with a solution of protecting polymer or micro-encapsulation. Alternatively, a chosen protective polymer may be made in a melted state and buffer particles are added. The melt is cooled and ground and milled to the desired particle size range. Alternatively, the buffering compound may be added to a solution of the protective polymer

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and removing the solvent by evaporation. The dried mass is compacted in a mold under high pressure and grinding or milling the compacted mass to the appropriate particle size range.

5       The resorbable spinal fusion device of the invention optionally includes a biological growth factor, e.g., bone morphogenic protein, to enhance bone cell growth. To protect the growth factor and to provide for controlled delivery, the biological growth factor may be itself compounded with a resorbable polymer by one of the many techniques available and prepared as a growth factor/polymer composite in pellet form, in small particle form or within the interstices or pores of a polymeric foam or low-density polymer and this polymer/growth factor composite deposited into void spaces of the resorbable spinal fusion device. Alternatively, the growth factor may simply be directly incorporated into the component formulation of the resorbable spinal fusion device.

10      Active periosteum cells, or other bony cells, may be also incorporated into a foam surrounding, or deposited in, the resorbable spinal fusion device so that the cells may facilitate bone cell fusion. To carry out such an incorporation, the periosteum surrounding a human bone is removed and cultured following standard cell culturing techniques. The scaffold for such periosteum cell growth is a resorbable polymer foam or mesh. This scaffolding is prepared by dipping the completed device in a polymer/solvent (such as PLGA dissolved in acetic acid). The so-wetted device is then frozen and subsequently freeze-dried (lyophilized) resulting in a foam layer (or coating) of polymer surrounding the device. After the periosteum cells have been grown in this foam layer, the device is incorporated into the spine for the enhancement of spinal fusion.

15      In another embodiment, the resorbable spinal fusion device may be prepared in such a manner as to exhibit a piezoelectric effect. It is known that oriented (molecularly aligned) biopolymers such as PLGA have piezoelectric

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characteristics. In addition, the oriented biopolymer poly-l-lactic acid (PLLA) has been shown to promote bone wound healing (Shimono et al., *In Vivo* 10:471-476, 1996 and Ikada et al., *J. Biomed. Mater. Res.* 30:553-558, 1996). To take advantage of this phenomenon, the resorbable polymer is first aligned, by drawing, for example, such that all polymer chains are essentially parallel. The spinal fusion device is then cut from this aligned polymeric material such that the polymer chains are at approximately a 45° angle to the surface of the device, this angle being known to produce the optimal piezoelectric effect. Buffers, reinforcement materials, growth factors, etc., may also be included in processing of the spinal fusion device to exhibit this phenomenon.

As described by White et al. (*Clinical Biomechanics of the Spine*, 2nd edition, 1990), there are four stages of maturation of the arthrodesis (spinal fusion): I, fibrous healing; II, mixed fibrous and osseous healing; III, immature osseous healing; and IV mature osseous healing. Stage I requires maximum protection with restricted activity and perhaps a protective orthosis. During stage II relatively less protection is required although with restricted activity. During stage III the patient is allowed normal but nonvigorous activity. In stage IV, maximum healing will be reached. For clinically stable patients the first three stages require about six weeks each, and stage IV, a minimum of six weeks. Clinically unstable patients require more time, especially for the first two stages. Thus the goals for duration and strength may be estimated.

A prototype device has been prepared for *in vitro* determination of weight loss and failure strength as a function of time. Due to the asymmetric design of the IFD, it is not feasible to measure the compressive modulus over time of the *in vitro* prototypes. This parameter, as well as failure and ultimate strength over time *in vitro*, has been measured on cylindrical discs of the same overall dimensions. *In vitro* experiments permit monitoring of the change in

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molecular weight in time for correlation with the mechanical measurements. Devices are tested for mechanical properties, e.g., compressive strength, compressive modulus, with equipment such as, e.g., the TA-XT2 Texture Analyzer (Texture Technologies Corporation) or the Instron 8511 Servo-Hydraulic System (Instron Corp.).

PLGA-85:15 (Resomer RG 858) including reinforcing fibers and HA buffer was molded at approximately 50°C under a force of 7-9 tons to form a translucent cylindrical rod 1.6 cm in diameter and 5.0 cm in length. Devices were then machined to the appropriate final dimensions, as discussed earlier. White and Panjabi (p. 29) report dimensions and stresses to which thoracic vertebrae are subject. The average area of the upper and lower end plates of T1 is about 340 mm<sup>2</sup>, and is subject to a loading force of about 2000 N. The compressive strengths of exemplary buffered and reinforced devices were, in all cases, greater than 13,000 N. Thus, the initial strength of these PLGA-85:15 devices is in excess of the stress to which cervical vertebrae will be subject and greater also than clinical targets of 10,000 N. Devices so made do not fracture at failure but rather irreversibly compress.

Figure 7 illustrates this phenomenon. Failure at 13 kN is indicated by a slowly rising load at displacements greater than about 1.5mm. If the tested device had failed by fracture, a rapid drop in load would have resulted. The design of the IFD and the PLGA comonomer ratio (i.e., lactide:glycolide ratio) enable the device to function through the four stages of healing with progressive loss of mass and strength. In clinically stable situations, at the end of stage I, the device should retain 70-80% of its mechanical strength, and at the end of stage II, 50% of its strength should be retained. During stages III and IV, further slow degradation will occur with complete resorption by one year.

Prototype devices have been prepared for feasibility trials with goats as the animal model. A viable model for

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testing fusion materials in the cervical spine is the *in vivo* goat model. Unlike most quadrupeds, the goat holds its head erect, thus loading the cervical vertebrae in a manner similar to humans. Although there are geometric differences, the relative sizes of the disc and vertebral bodies are similar to those of the human. (Pintar et al., Spine 19:2524-2528, 1994; Zdeblick et al., Spine 17(105):5418-5426, 1992.) The goat is thus the animal model of choice for testing the spinal fusion device of the invention.

The experimental procedure followed in the *in vivo* goat model is as follows. Anesthetized animals undergo implantation via a surgery to the anterior cervical spine (Pintar et al., Spine 19:2524-2528, 1994). After exposing the lower 5 cervical segments, discectomy is performed at four levels. Two resorbable IFD's filled with cancellous bone are placed in two of these spaces, the others receive a piece of tricortical iliac bone graft in place. The bone graft and cancellous bone are harvested from the goat iliac crest through a separate incision over the hip bone. Placement of the IFD or the graft in upper or lower sites is alternated for each animal with an intact disc space between implants. The operative sites are closed, and the animals allowed to recover.

At sacrifice, the spinal column of the goat is excised leaving the intact ligamentous column. The cervical and lumbar sites are separated and radiographed before mounting for biomechanical (as described above) or histological analyses for resorptive activity and new bone formation. The fusion rate and biomechanical stiffness are evaluated for spinal units harvested from the goats. Spinal units undergo radiographic imaging to assess fusion, biomechanical testing to assess strength, and histological analysis to assess tissue changes. The results are compared to conventional graft-based spacers and fusion devices.

PLGA implants can be effectively reinforced by the use of degradable scaffolds which are molecularly dispersed in the host PLGA polymer. For example, a solid solution

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containing PLGA, poly(propylene fumarate) (PPF), and vinyl pyrrolidinone (VP) as a crosslinking agent (or other vinyl monomer) may be heated with an initiator (such as benzoyl peroxide). The PPF chains are crosslinked by VP to form an interpenetrating network of crosslinked PPF and PLGA polymer chains. Following heating, further crosslinking is possible using  $\gamma$ -irradiation, e.g. 2.5 mrad.

Several reinforcement techniques described in the literature include self-reinforcement using aligned PLGA fibers (Vainionpaa et al., *Biomaterial* 8:46-48, 1987; Pihlajamaki et al., *J. Bone and Joint Surgery* 74:13:853-857, 1992; Ashammakhi et al., *J. Biomedical Materials Research* 29: 687-694, 1995) and reinforcement with calcium phosphate glass fibers (R.A. Casper et al., *Polym. Mater. Sci. Eng.* 53:497-501, 1985).

Reinforcement can also be achieved according to the invention by molding a rod of rectangular or other suitable cross-section that contains fibers under tension using the mold and ram assembly of the invention, as shown in Figs. 6A-6G. Referring to Fig. 6A, mold cavity 61 and ram 62 are rectangular in cross-section in the illustrated embodiment. The mold illustrated is constructed of five plates (front face plate 63, rear face plate 64, side plates 65 and bottom plate 66), suitably fastened or bonded together. The front and rear face plates 63, 64 are machined or otherwise formatted, as will be described below, with key holes 60 to receive holder assemblies for the reinforcing fibers, which comprise front and rear tension tubes, front and rear tension tube caps, serrated discs, and a front tension tube threaded nut.

Referring to Fig. 6B (an edge view of front face plate 63) and Fig. 6C (a plan view of front face plate 63), the inside face 67 of plate 63 contains a circular recess 68, with associated slots 69. Recess 68 adjoins a larger recess 70 that extends to the outside face 71 of front face plate 63. Recess 70 includes associated slots 72. The axis between slots 72 is perpendicular to the axis between slots

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69. A smaller diameter recess stop 73 separates recess 68 from recess 70. Rear face plate 64 is similarly configured.

Referring now also to Figs. 6D-G, the mold is assembled for use as follows. A disc 75 (Fig. 6D) having serrated slots 76 is threaded with polymer fibers 88, which are distributed throughout the serrated slots. The distribution of the fibers is spatially maintained by the serrations. Referring also to Fig. 6G, discs 75 with fibers in place are mounted in recesses 68 in the front and rear face plates 63, 64 of the assembled mold. Orientation of discs 75 is maintained by vanes 77 on the sides of the discs, which fit into slots 69. Alternatively, discs 75 may be mounted first in face plates 63, 64 and threaded in place. The protruding fiber bundles are then threaded through front and rear tension tube assemblies 78, 79, which are positioned in recesses 70 in the front and rear face plates 63, 64, respectively. Tension tube assemblies 78, 79 consist of tension tubes 80, each having vanes 82 which fit into slots 72 in the front and rear face plate recesses 70, respectively, thus maintaining the orientation of the tubes. The tension tubes are closed with caps 83 to complete assemblies 78, 79. The fiber bundles are threaded additionally through holes 84 in the front and rear tension tube caps, as they exit the tension tubes. Holes 84 are off-center and below the axis of the tension tubes. This configuration holds the fibers against the serrations of the discs. Outside the caps, the fibers may be knotted to keep them from slipping back through the holes. Other methods of anchoring the fibers may be used. For example, a bead of cement (such as epoxy or cyanoacrylate adhesives) may be built up on the outside of the caps to keep the fibers from slipping through. Also referring to Figs. 6E and 6F, it can be seen that the tension tube 80 of front tension tube assembly 78 is exteriorly threaded 85 along its length and equipped with a nut 86 which, when tightened against the face plate, pulls the tension tube partially out of the face plate, thus putting the fibers under tension.

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To prepare a reinforced resorbable spinal fusion device, mold cavity 61 of the assembled mold is then filled with the appropriate powdered formulation. The powdered formulation may be evenly distributed among the fibers by placing the mold on a vibrator. Ram 62 is put in place, in the opening of the mold, and pressure is exerted. The mold may be heated externally with heating tapes, or it may be so machined as to have recesses for cartridge heaters. When the molding process is complete, the tension on the reinforcing fibers is released, and the completed device is removed from the mold.

While the present invention has been described in conjunction with a preferred embodiment, one of ordinary skill, after reading the foregoing specification, will be able to effect various changes, substitutions of equivalents, and other alterations to the compositions and methods set forth herein. It is therefore intended that the protection granted by Letters Patent hereon be limited only by the definitions contained in the appended claims and equivalents thereof.

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CLAIMS

What is claimed is:

- 5        1. A resorbable interbody spinal fusion device for spinal fixation, said device comprising 25-100% resorbable material.
- 10      2. The resorbable interbody spinal fusion device of claim 1, further comprising one or more void spaces therein.
- 15      3. The resorbable interbody spinal fusion device of claim 2, wherein one of said one or more void spaces contains a grafting material for facilitating bony development and/or spinal fusion.
- 20      4. The resorbable interbody spinal fusion device of claim 3, wherein said grafting material is an autologous grafting material.
- 25      5. The resorbable interbody spinal fusion device of claim 1, wherein said device is shaped substantially as a tapered wedge or cone.
- 30      6. The resorbable interbody spinal fusion device of claim 1, wherein said device is shaped substantially as a threaded screw.
- 35      7. The resorbable interbody spinal fusion device of claim 1, wherein said device is shaped substantially as a threaded rod of cruciform configuration.
- 40      8. The resorbable interbody spinal fusion device of claim 5, further comprising at least one serrated or threaded outer face.
- 45      9. The resorbable interbody spinal fusion device of claim 1, wherein said resorbable material is a polymer producing

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acidic products or low molecular weight resorbable fragments upon hydrolytic degradation.

10. The resorbable interbody spinal fusion device of claim  
5, wherein said resorbable material further comprises a buffering or neutralizing agent in sufficiently high concentration to moderate the rate of change of pH of said resorbable material during resorption.

10. The resorbable interbody spinal fusion device of claim  
1, wherein said resorbable material is a polymer selected  
from the group consisting of polydioxanone, poly( $\epsilon$ -caprolactone), polyanhydride, polyester, copoly(ether-ester),  
polyamide, polylactone, poly(propylene fumarate), and  
combinations thereof.  
15

12. The resorbable interbody spinal fusion device of claim  
11, wherein said bioerodible polymer comprises poly(lactide-  
co-glycolide) with a lactide to glycolide ratio in the range  
of 0:100% to 100:0% inclusive.  
20

13. The resorbable interbody spinal fusion device of claim  
10, wherein said buffering or neutralizing agent is a polymer  
comprising at least one basic group.  
25

14. The resorbable interbody spinal fusion device of claim  
13, wherein said polymer comprising at least one basic group  
is selected from the group consisting of polyamines,  
polyesters, vinyl polymers, and copolymers of acrylic acid.  
30

15. The resorbable interbody spinal fusion device of claim  
10, wherein said buffering or neutralizing agent is a compound  
that, on exposure to water, hydrolyzes to form a base.  
35

16. The resorbable interbody spinal fusion device of claim  
10, wherein said buffering or neutralizing agent is selected

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from the group consisting of carbonates, phosphates, acetates, succinates and citrates.

5 17. The resorbable interbody spinal fusion device of claim 1 wherein said resorbable material further comprises reinforcing fibers.

10 18. The resorbable interbody spinal fusion device of claim 17, wherein said reinforcing fibers are made of said resorbable material.

15 19. The resorbable interbody spinal fusion device of claim 10, wherein said resorbable material further comprises reinforcing fibers.

20 20. The resorbable interbody spinal fusion device of claim 19, wherein said reinforcing fibers are made of said buffering or neutralizing agent.

25 21. A substantially wedge shaped resorbable interbody spinal fusion device, wherein said device is substantially manufactured from a resorbable material poly(d,l-lactide-co-glycolide), said device further comprising a buffering or neutralizing agent wherein said buffering or neutralizing agent is hydroxyapatite, and wherein said device further comprises one or more void spaces therein.

30 35 22. A resorbable interbody spinal fusion device, said device shaped substantially as a threaded screw, wherein said device is substantially manufactured from a resorbable material poly(d,l-lactide-co-glycolide), said device further comprising a buffering or neutralizing agent wherein said buffering or neutralizing agent is hydroxyapatite, and wherein said device further comprises one or more void spaces therein.

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23. A method of making a resorbable interbody spinal fusion device, comprising the steps of:

providing a mold for said resorbable interbody spinal fusion device;

5 orienting reinforcing fibers under tension in said mold; introducing a resorbable material into said mold; molding said resorbable material under pressure; and releasing tension on said reinforcing fibers prior to removing said device from said mold.

10

24. The method of claim 23 wherein said resorbable reinforcing fibers are made of the same material as said resorbable interbody material.

15

25. The method of claim 23 wherein said resorbable reinforcing fibers do not contain a buffer.

20

26. The resorbable interbody spinal fusion device of claim 10 wherein said buffering or neutralizing agent is selected from the group consisting of compounds wherein the pKa of the conjugate acids of said compounds is greater than the pKa of acids produced by hydrolysis of the polymer(s) from which said device is prepared.

25

27. The resorbable interbody spinal fusion device of claim 1, wherein said device is fabricated from at least two resorbable polymers.

30

28. The resorbable interbody spinal fusion device of claim 27, wherein one of said resorbable polymers is poly (propylene fumarate).

35

29. The resorbable interbody spinal fusion device of claim 27, wherein one of said resorbable polymers has been cross-linked in the presence of a crosslinking agent and an initiator, whereby said crosslinked resorbable polymer forms a reinforcing interpenetrating network.

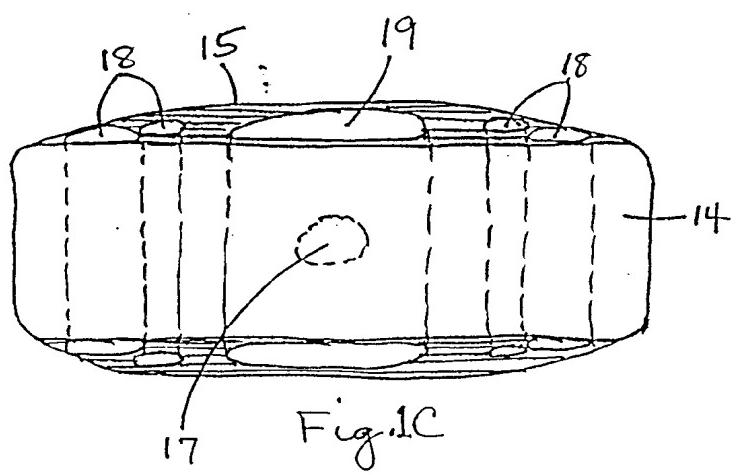
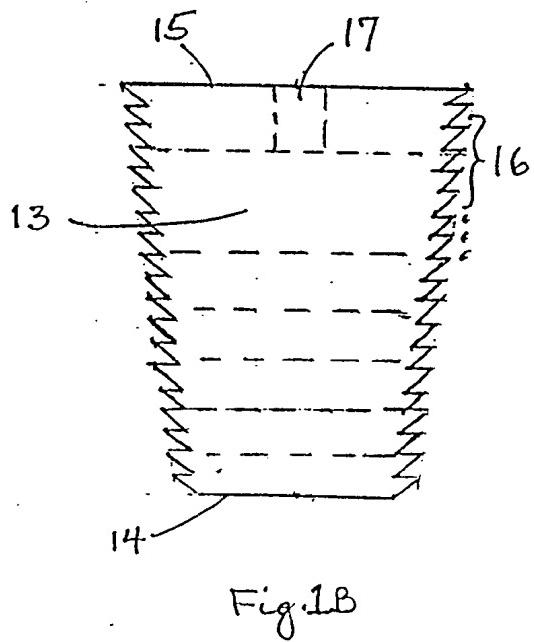
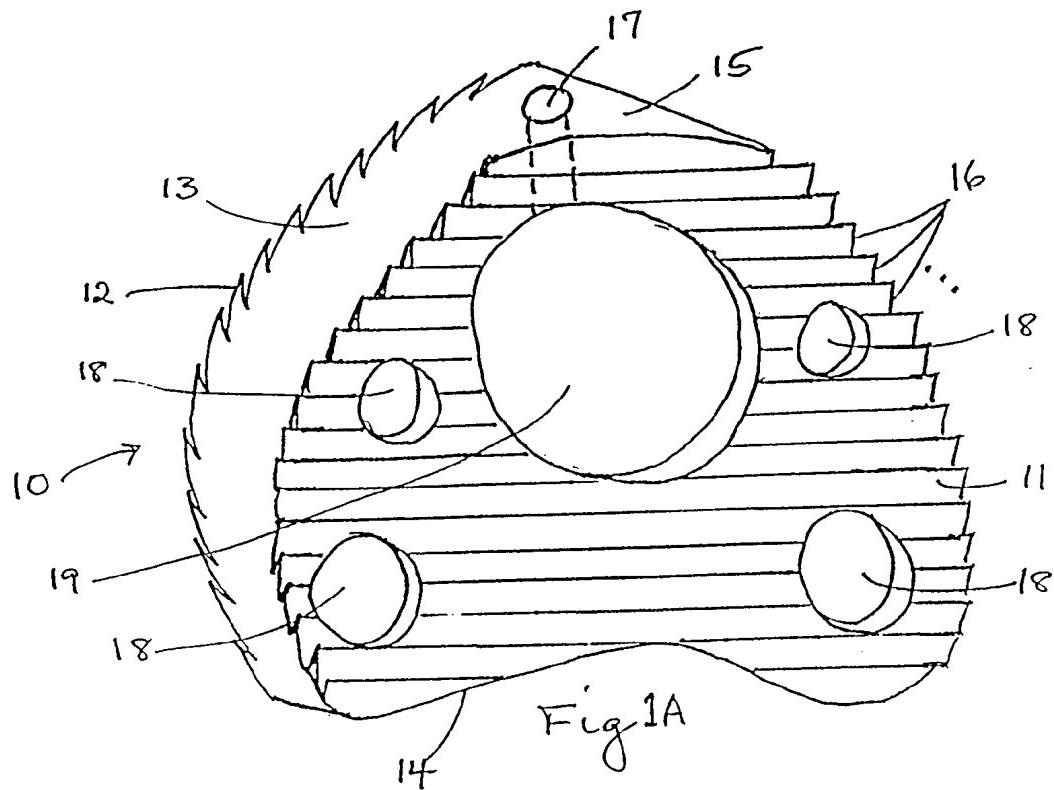
-28-

30. The resorbable interbody spinal fusion device of claim 29, wherein said crosslinking agent is vinyl pyrrolidone.

5 31. The resorbable interbody spinal fusion device of claim 29, wherein said initiator is benzoyl peroxide.

10 32. The resorbable interbody spinal fusion device of claim 1, wherein said device is fabricated from a polymer wherein molecular chains of said polymer have been aligned to be essentially parallel.

15 33. The resorbable interbody spinal fusion device of claim 32, wherein said device has been cut such that the aligned polymer molecular chains are at approximately a 45° angle to a surface of said device.



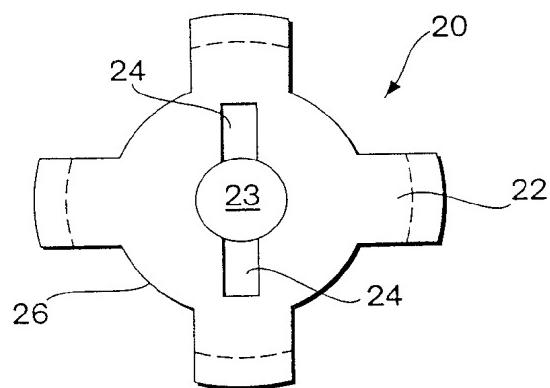


Fig. 2A

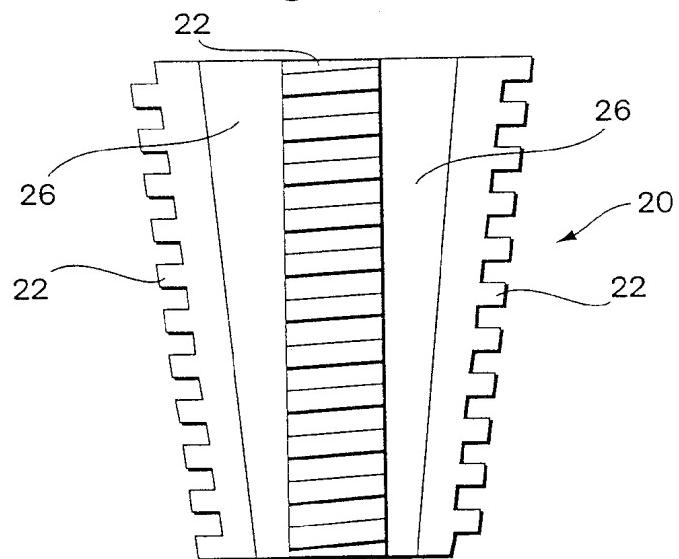


Fig. 2B

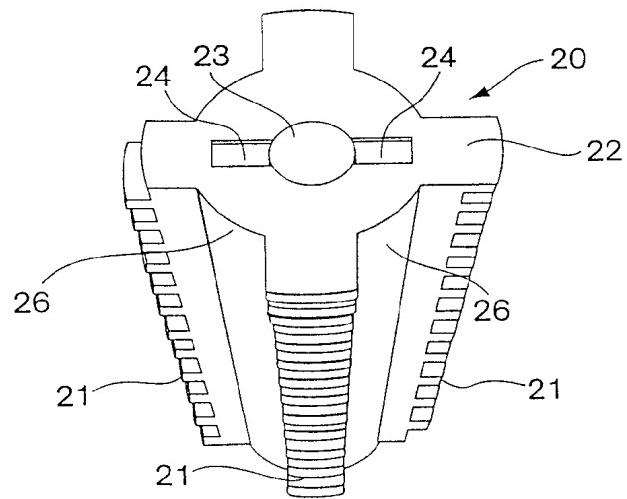


Fig. 2C

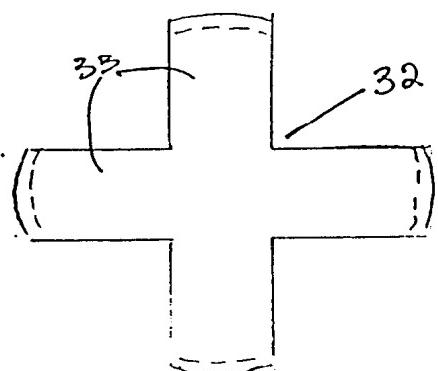


Fig. 3A

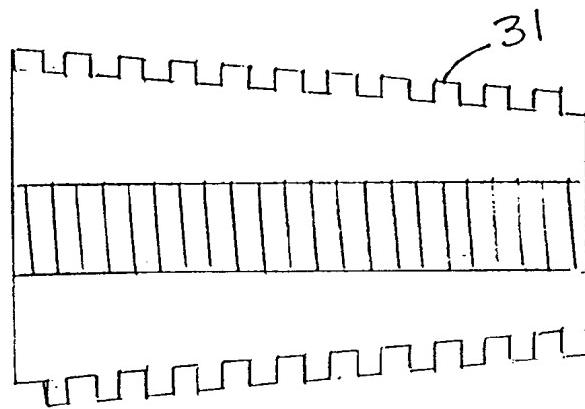


Fig. 3B

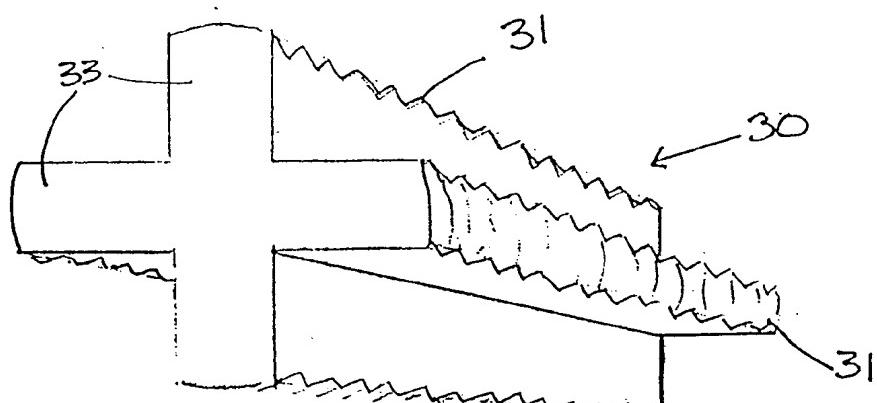


Fig. 3C

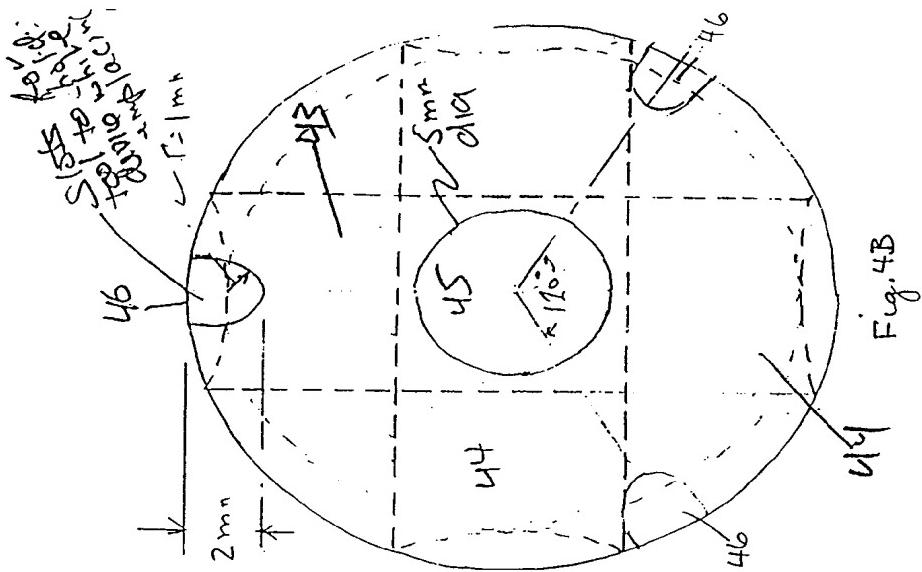


Fig. 4B

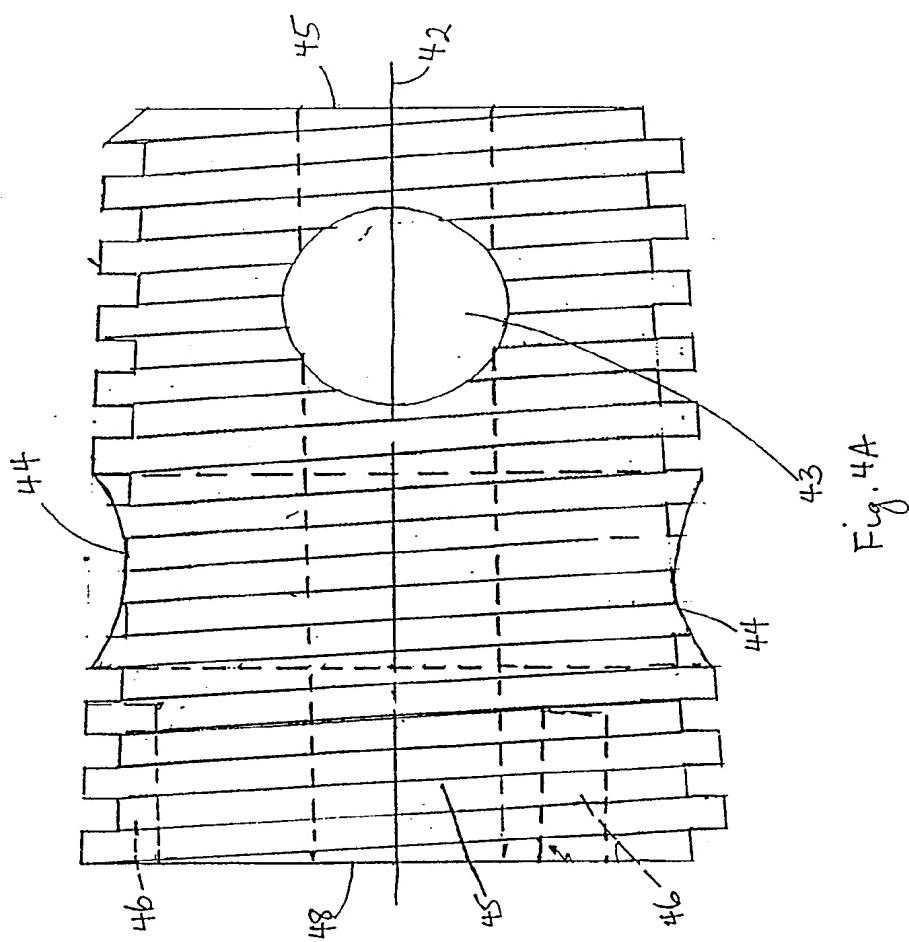
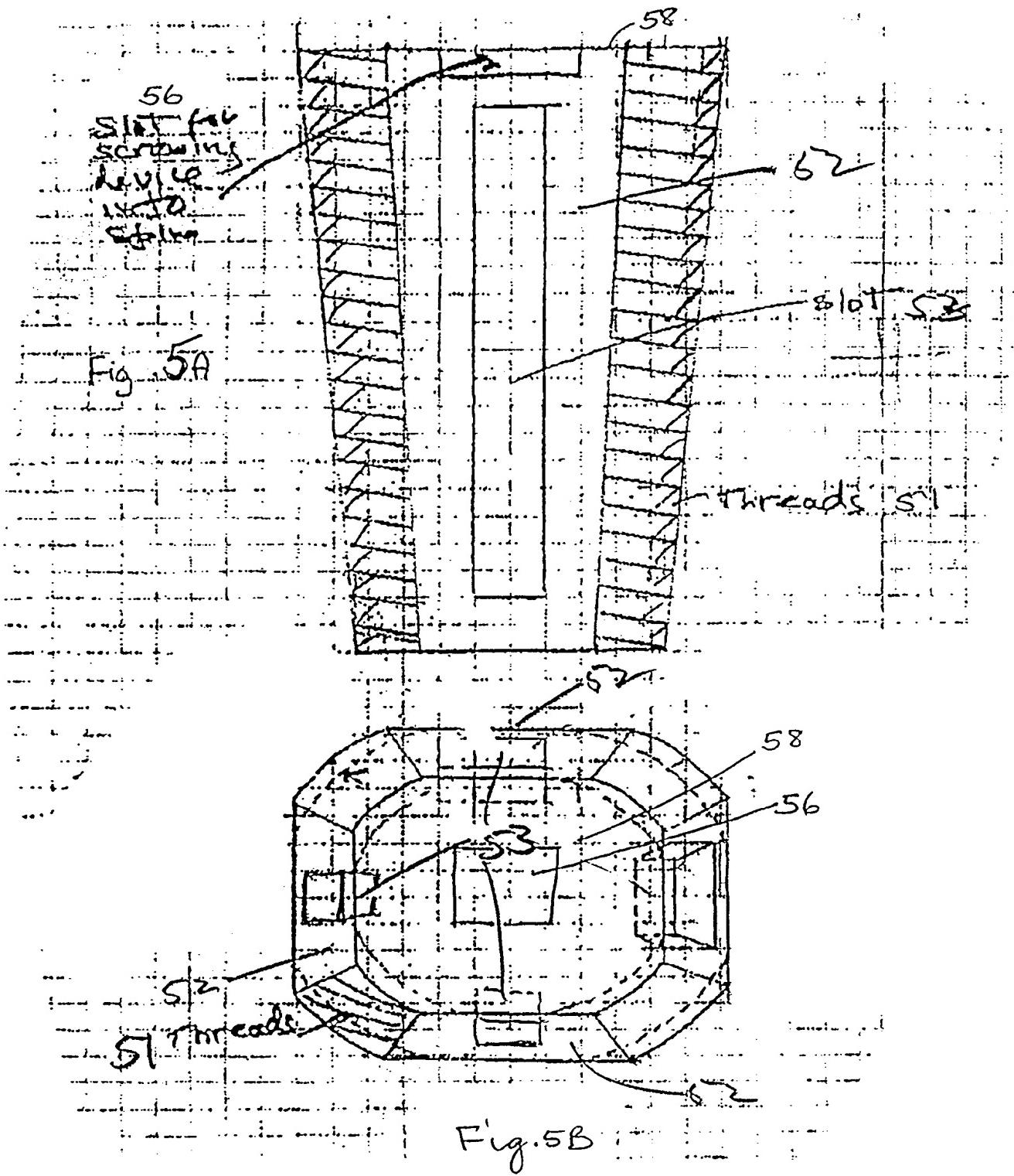


Fig. 4A



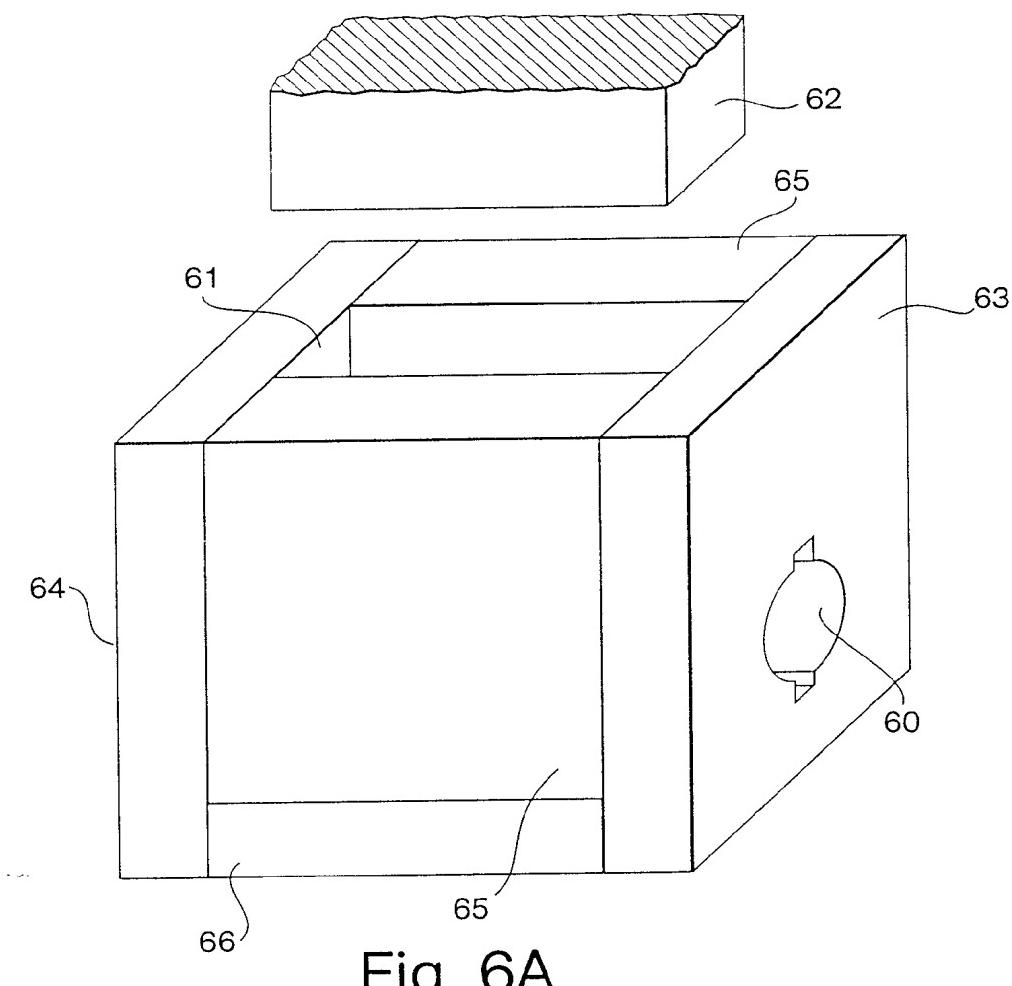


Fig. 6A

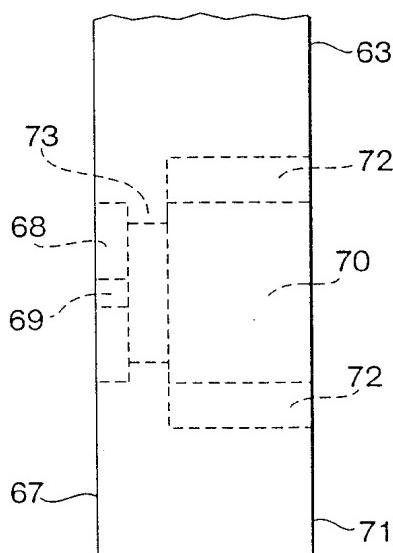


Fig. 6B

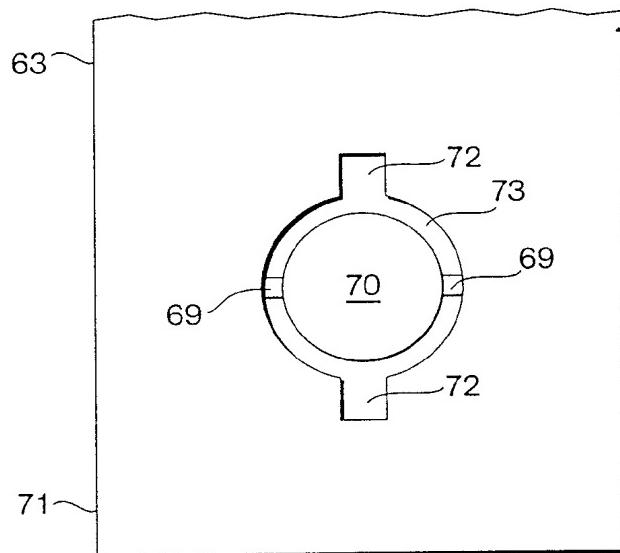


Fig. 6C

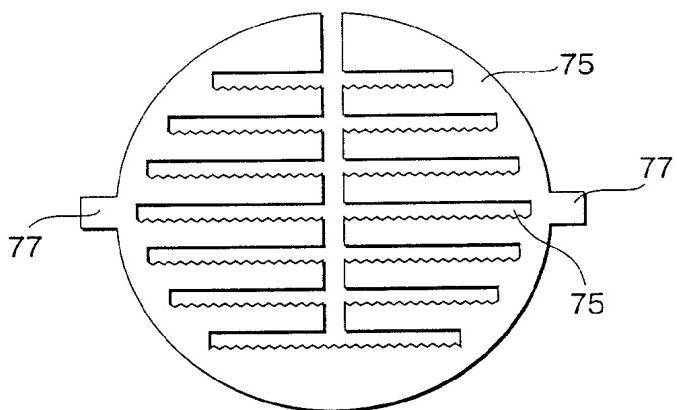


Fig. 6D

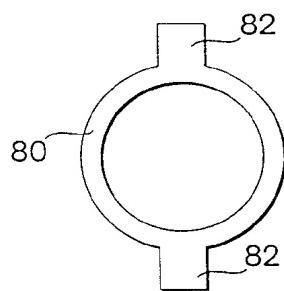


Fig. 6E

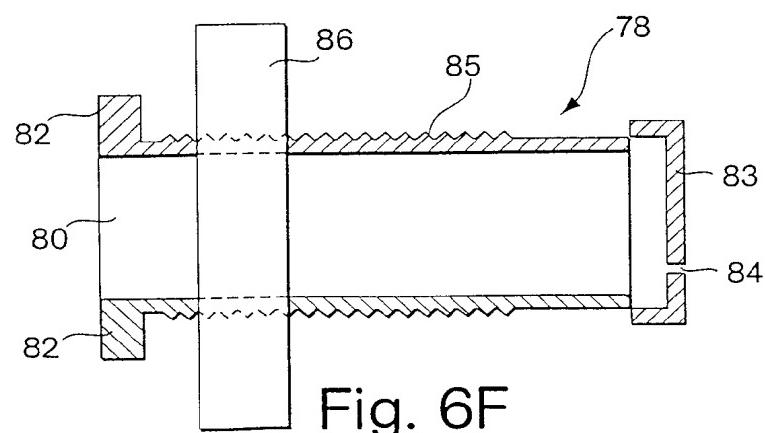


Fig. 6F

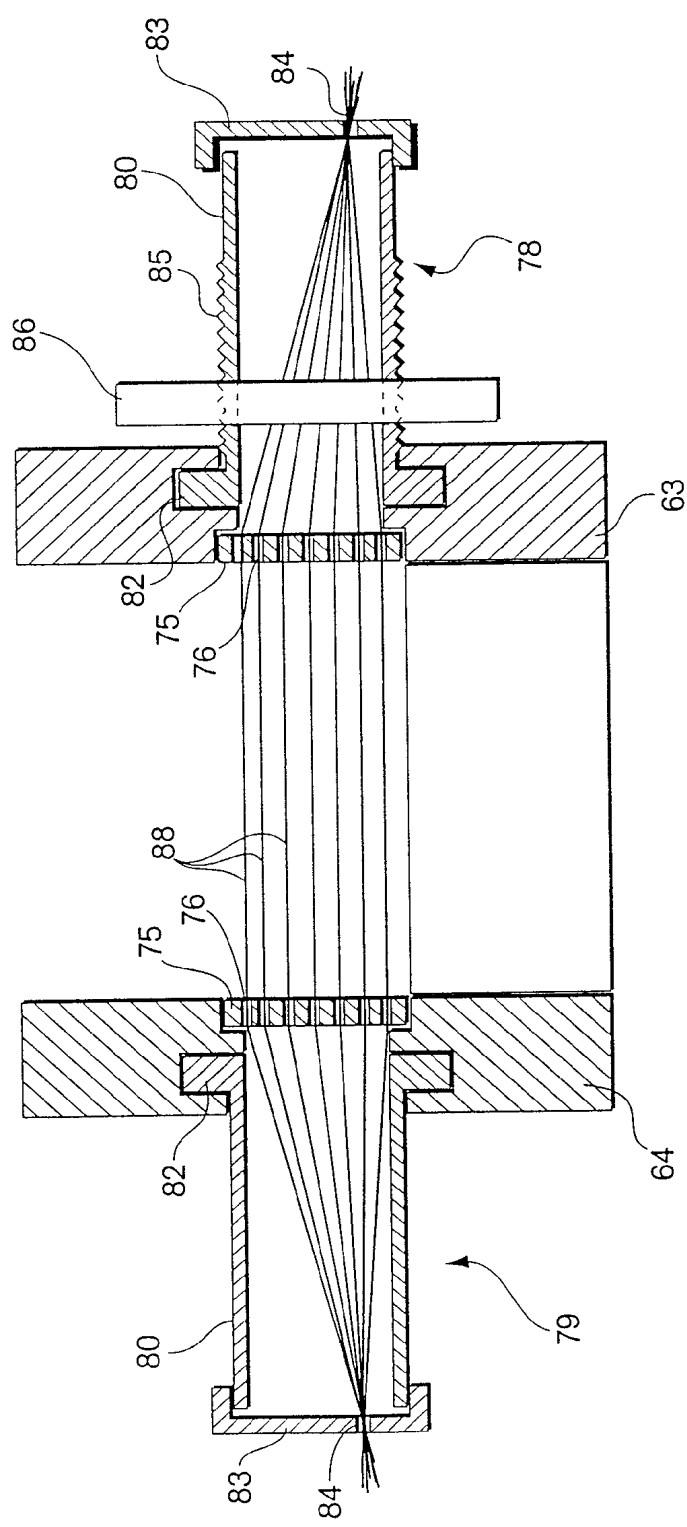


Fig. 6G

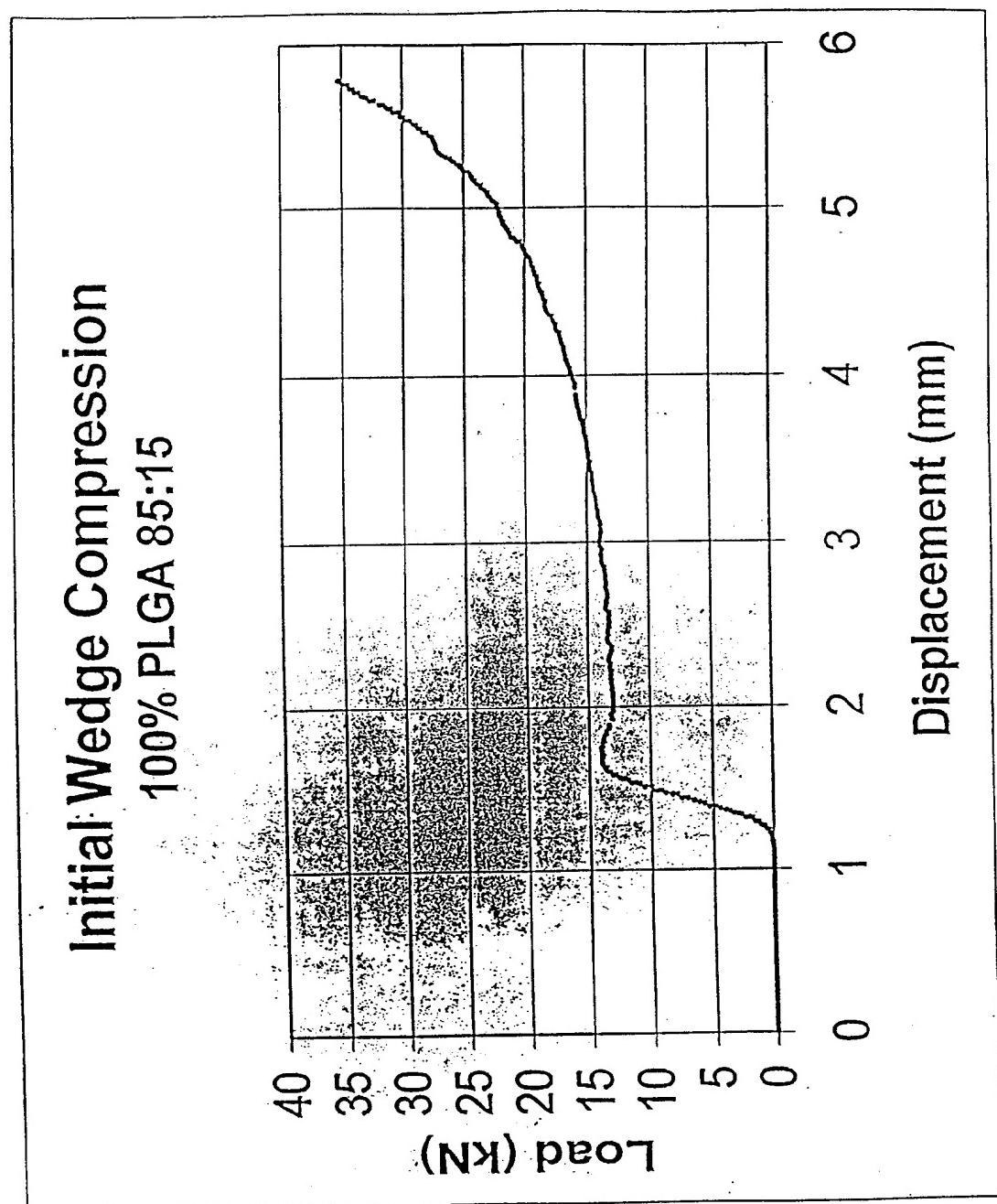


Fig. 7

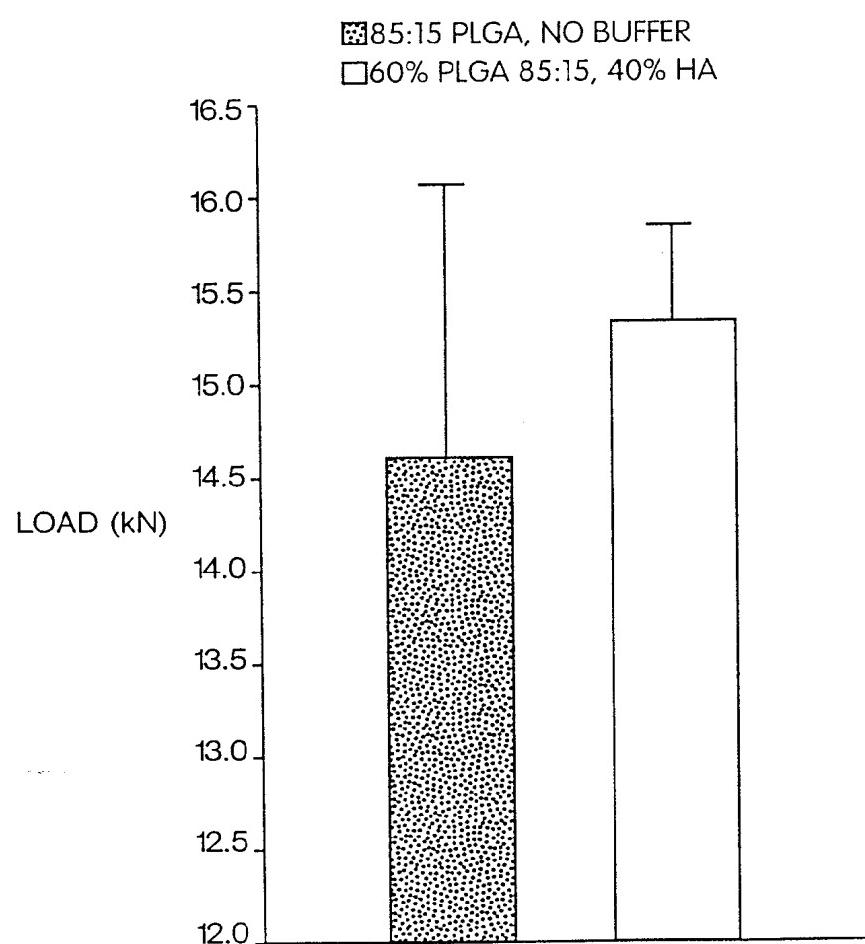


Fig. 8

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US98/16650

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61F 2/44

US CL : 623/17

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606,65, 77; 623/17

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

Please See Extra Sheet.

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,225,129 A (VAN DEN BERG) 06 July 1993, entire document especially col. 6 lines 21-49, and claims 19-24.	23-25
X	US 5,527,864 A (SUGGS et al) 18 June 1996, entire document.	1, 27-31
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Y		32, 33
X	US 5,522,895 A (MIKOS) 04 June 1996, entire document.	1-3, 9, 11, 12
---		-----
Y		5-8
Y	US 4,349,921 A (KUNTZ) 21 September 1982, entire document.	5-8

 Further documents are listed in the continuation of Box C.

See patent family annex.

\* Special categories of cited documents:

"T"

later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

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"X"

document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

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"A"

document member of the same patent family

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

Date of the actual completion of the international search

14 SEPTEMBER 1998

Date of mailing of the international search report

19 OCT 1998

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International application No.  
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## C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4,655,777 A (DUNN et al) 07 April 1987, entire document.	1, 9-13, 15-20, 26, 27 -----
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Y		33
Y	US 4,968,317 A (TORMALA et al) 06 November 1990, entire document.	32

**INTERNATIONAL SEARCH REPORT**

International application No. PCT/US98/16650
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**B. FIELDS SEARCHED**

Electronic data bases consulted (Name of data base and where practicable terms used):

APS

Search Terms: (resorbable or bioresorbable or absorbable or bioabsorbable or degradable or biodegradable) and buffer? and (glycoli? or lacti? or polyglycol? or polylacti?); and propylene fumarate. search terms: 264/257/ccis and (resorbable or bioresorbable or absorbable or bioabsorbable or degradable or biodegradable).



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(54) Title: PARTIAL DISCAL PROSTHESIS

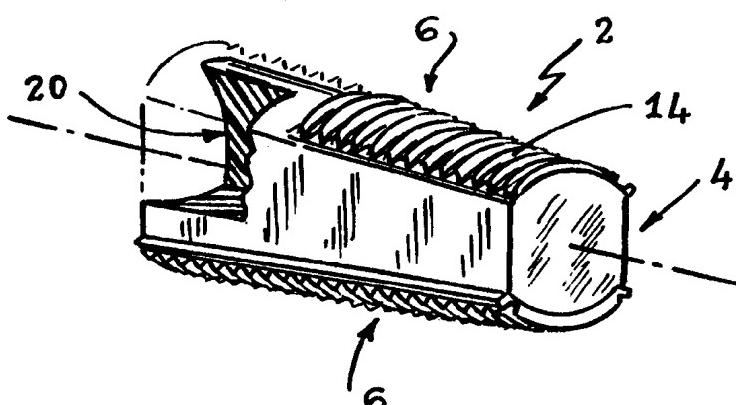
(54) Titre: PROTHESE DISCALE PARTIELLE

## (57) Abstract

The invention concerns a prosthesis (2) designed to be inserted between two neighbouring vertebrae, comprising a core (4) made of an elastic material and covered, over part of its periphery, with a rigid material coating (6) designed to be in contact with the two neighbouring vertebrae. The core (4) comprises, in transverse cross-section, two end portions (8) linked by a median portion (12) and said coating includes two caps (6) provided with a threading and covering respectively at least partially the external periphery of said end portions (8), the distance separating said caps increasing towards the prosthesis front part. Said prosthesis can easily be inserted and has excellent stability inside the intervertebral space.

## (57) Abrégé

Cette prothèse (2), destinée à être insérée entre deux vertèbres voisines, comprend une âme (4) réalisée en un matériau élastique et recouverte, sur une partie de sa périphérie, par un enrobage (6) en matériau rigide destiné à être en contact avec les deux vertèbres voisines. L'âme (4) comprend, en coupe transversale, deux portions d'extrémité (8) reliées par une portion médiane (12) et ledit enrobage comprend deux coiffes (6) pourvues d'un filetage et recouvrant respectivement au moins partiellement la périphérie externe desdites portions d'extrémité (8), la distance séparant lesdites coiffes augmentant vers la partie antérieure de la prothèse. Cette prothèse peut facilement être mise en place et possède une excellente stabilité au sein de l'espace intervertébral.



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## PROTHESE DISCALE PARTIELLE

La présente invention concerne une prothèse discale partielle.

De manière habituelle, les prothèses discales, qui peuvent être partielles ou totales, sont destinées à remplacer tout ou partie d'un disque intervertébral lorsque ce dernier a été détruit par la chirurgie ou par la maladie.

Un premier type de prothèse discale consiste en une cage rigide, qui peut être par exemple de section transversale rectangulaire, dans laquelle sont ménagées des perforations propres à recevoir des greffons destinés à assurer une solidarisation satisfaisante de cette cage avec les deux vertèbres entre lesquelles elle doit être insérée. Ce type de cage rigide, qui est implantée notamment par impactage ou par vissage, présente un inconvénient en ce sens qu'elle conduit à un blocage complet des deux vertèbres entre lesquelles est disposée la cage, ce qui limite la liberté de mouvement du patient.

On connaît également, par le document EP-A-0 346 269, une prothèse de disque intervertébral formée par une âme en matériau viscoélastique intercalée entre deux plaques de recouvrement métalliques, qui sont destinées à être en contact, une fois implantées, avec la surface des vertèbres. Il existe cependant un inconvénient lié à ce type de prothèse, qui réside notamment dans son manque de stabilité, de sorte que cette prothèse possède de forts risques d'être éjectée de l'espace intervertébral.

Afin de pallier les inconvénients de l'art antérieur évoqués ci-dessus, l'invention se propose de réaliser une prothèse discale partielle, qui puisse être antérieure ou postérieure, dont la mise en place dans l'espace intervertébral soit aisée, qui possède une stabilité satisfaisante au sein de cet espace intervertébral et qui permette une liberté de mouvement suffisante tout en garantissant le maintien d'une posture physiologiquement avantageuse.

A cet effet, l'invention a pour objet une prothèse discale partielle destinée à être insérée entre deux vertèbres voisines, du type comprenant une âme réalisée en un matériau élastique tel qu'un polymère de silicium ou un élastomère, recouvr-

te, sur une partie de sa périphérie, par un enrobage réalisé en un matériau rigide et destiné à être en contact avec lesdites deux vertèbres voisines, caractérisée en ce que ladite âme comprend, en coupe transversale, deux portions d'extrémité reliées par une portion médiane, ledit enrobage comprend deux coiffes pourvues d'un filetage et recouvrant au moins partiellement la périphérie externe desdites portions d'extrémité, et la distance séparant lesdites coiffes augmente vers la partie antérieure de la prothèse.

L'invention se propose également de réaliser un outil de pose pour la prothèse telle que décrite ci-dessus, qui assure une implantation aisée de cette dernière, qui puisse être facilement retiré une fois la prothèse implantée et qui permette de préserver l'intégrité des différents organes au voisinage desquels cet outil est déplacé durant l'ensemble de ces opérations.

A cet effet, l'invention a également pour objet un outil de pose pour la prothèse telle que décrite ci-dessus, caractérisé en ce qu'il comprend un manche de préhension prolongé par des moyens propres à solidariser ladite prothèse par rapport audit outil dans un état transversalement comprimé de ladite prothèse.

L'invention va être décrite ci-dessous, en référence aux dessins annexés, donnés uniquement à titre d'exemple non limitatif et dans lesquels :

- la figure 1 est une vue en perspective partiellement arrachée d'un premier mode de réalisation d'une prothèse discale conforme à l'invention ;

- les figures 2 et 3 sont des vues éclatées en bout représentant respectivement les parties avant et arrière de la prothèse représentée à la figure 1 ;

- la figure 4 est une vue schématique en perspective, avec arrachement, d'un outil de pose pour la prothèse représentée aux figures 1 à 3 ;

- la figure 5 est une vue en perspective montrant la prothèse des figures 1 à 3 engagée dans l'outil de pose de la figure 4 ;

- la figure 6 est une vue en coupe suivant la ligne

VI-VI à la figure 5 ;

- la figure 7 est une vue schématique illustrant l'implantation de la prothèse des figures 1 à 3 ;

5 - la figure 8 est une vue schématique illustrant la désolidarisation de l'outil de pose de la figure 4, par rapport à la prothèse des figures 1 à 3, après implantation de cette dernière ;

10 - la figure 9 est une vue schématique en perspective d'une prothèse conforme à un deuxième mode de réalisation de l'invention ;

- la figure 10 est une vue en coupe axiale d'une prothèse conforme à un troisième mode de réalisation de l'invention ;

15 - la figure 11 est une vue en coupe axiale d'un quatrième mode de réalisation d'une prothèse discale conforme à l'invention ;

- les figures 12 et 13 sont des vues en bout représentant respectivement les parties avant et arrière de la prothèse de la figure 1 ;

20 - la figure 14 est une vue schématique en perspective, avec arrachement, des différents éléments constitutifs d'un outil de pose pour la prothèse représentée aux figures 11 à 13 ;

25 - la figure 15 est une vue en coupe longitudinale illustrant la solidarisation de l'outil de pose de la figure 4 et de la prothèse des figures 11 à 13 ;

30 - la figure 16 est une vue partielle en bout, illustrant les languettes dont est pourvue la prothèse représentée aux figures 11 à 13, lorsque cette dernière est implantée ;

- la figure 17 est une vue analogue à la figure 16, illustrant la position respective des languettes de la prothèse en vue du retrait de cette dernière ;

35 - la figure 18 est une vue en perspective d'un cinquième mode de réalisation d'une prothèse discale conforme à l'invention ;

- les figures 19 et 20 sont des coupes longitudinales suivant la ligne XIX-XIX à la figure 18, dans des positions

respectivement de repos et de compression de la prothèse de cette figure 18 ;

- les figures 21 et 22 sont des coupes transversales suivant la ligne XXI-XXI à la figure 18, dans des positions respectivement de repos et de compression de la prothèse de cette figure 18 ;

- la figure 23 est une vue en perspective avec arrachement d'une âme composite d'une prothèse conforme à l'invention et

- la figure 24 est une vue en coupe longitudinale d'une âme formée de plusieurs éléments appartenant à une prothèse conforme à l'invention.

Comme le montrent les figures 1 à 3, la prothèse discale conforme à l'invention et désignée dans son ensemble par la référence 2, comprend une âme 4 dont la surface extérieure est partiellement recouverte au moyen de deux enrobages formées par des coiffes 6. L'âme 4 est réalisée en un matériau élastique biocompatible, comme par exemple un polymère de silicium ou un caoutchouc précontraint. Les coiffes 6 sont exécutées en un matériau rigide biocompatible tel que par exemple en acier spécial, notamment du titane, et sont assujetties à l'âme par exemple par une colle de silicium ou autre.

Comme le montrent en particulier les figures 2 et 3, la section de l'âme 4 se compose de deux portions d'extrémités 8 dont la périphérie extérieure décrit un arc de cercle, qui sont reliées par deux méplats 10 formant une partie médiane 12.

Un renflement 20 en forme de coupelle est ménagé dans l'extrémité avant de l'âme 4, et constitue une amorce de flexion, comme cela sera visible dans la suite de la description.

Chaque coiffe 6 est réalisée sous forme d'un profilé présentant, en coupe transversale, une forme d'arc de cercle. Ces coiffes recouvrent la totalité de la périphérie extérieure des portions d'extrémités 8 de l'âme 4, alors que les méplats 10 ne sont pas recouverts. La surface extérieure de ces coiffes est munie d'un filetage 14 destiné à faciliter l'implantation de la prothèse, comme cela sera explicité dans ce qui suit.

La surface extérieure des coiffes 6 possède en outre des

irrégularités formées par exemple par gaufrage ou frittage, qui sont destinées à garantir une bonne stabilité de la prothèse une fois montée. Des rainures axiales 16 sont en outre ménagées sur la totalité de la longueur de chaque coiffe, au voisinage 5 de chaque bordure 18 de ces dernières.

Il convient de noter que la dimension transversale ou largeur D des portions d'extrémité 8 est sensiblement constante tout le long de la prothèse, alors que la dimension ou hauteur H des méplats 10 reliant ces portions d'extrémité, augmente 10 vers l'avant de la prothèse, en faisant référence à la prothèse une fois montée sur un patient.

La distance séparant les coiffes augmente vers l'avant de la prothèse. On entend par distance séparant les coiffes la distance maximale, en coupe transversale, séparant, dans la 15 position comprimée de la prothèse, les zones de contact respectives des coiffes avec les vertèbres.

A titre indicatif, la longueur de la prothèse, à savoir la distance séparant ses extrémités avant et arrière, est par exemple de l'ordre de 16 à 20 mm, sa hauteur H minimale au niveau de la partie arrière de la prothèse, est de l'ordre de 20 12 mm, alors que sa hauteur H maximale est de l'ordre de 16 mm. Le rayon de courbure de la partie intérieure de chaque coiffe est par exemple voisin de 12 mm, et ces coiffes s'étendent sur un secteur angulaire de l'ordre de 120° chacune. Enfin, 25 l'épaisseur des coiffes est par exemple de 2 mm environ.

La figure 4 représente un outil désigné dans son ensemble par la référence 22, destiné à la pose de la prothèse 2 au sein de l'espace intervertébral d'un patient. Cet outil 22 comprend un manche cylindrique 24 allongé dont les dimensions sont appropriées pour conférer une préhension aisée par un chirurgien. Ce manche 24 est percé d'un orifice central co-axial 26, dont les dimensions transversales sont inférieures à celles de la partie arrière de la prothèse 2. Cet orifice 26 est propre 30 au passage d'une tige 27, comme cela sera explicité dans ce qui suit.

Le manche 24 est terminé par deux languettes 28 symétriques l'une de l'autre réalisées sous forme d'un profilé mince en forme d'arc de cercle. Ces languettes possèdent un rayon de 35

courbure voisin de celui des coiffes 6 de la prothèse et s'étendent sur des secteurs angulaires dont la valeur, ajoutée à celle des secteurs angulaires des coiffes 6, est légèrement supérieure à 360°. Des nervures axiales 30 font saillie vers l'intérieur sur l'intégralité de la longueur de chaque languette, au niveau de chacune des bordures 32 de celle-ci, comme le montre en particulier la figure 6. Les dimensions transversales de ces nervures sont telles qu'elles sont propres à se loger dans les rainures 16 ménagées dans les coiffes 6.

La dimension longitudinale des languettes 28 est analogue, voire très légèrement supérieure, à celle de l'ensemble de la prothèse 2.

Les figures 5 et 6 représentent la prothèse 2 engagée dans le volume cylindrique défini par les languettes 28 de l'outil de pose 22. En vue du montage de la prothèse, il convient tout d'abord d'engager l'extrémité des nervures 30, opposée au manche 24, dans l'extrémité arrière des rainures 16. Puis, il s'agit de comprimer, par exemple manuellement, l'avant de la prothèse, ce qui est possible à la fois du fait de la nature élastique de l'âme 4 et de la présence du renforcement 20. Puis, on fait coulisser chaque nervure 30 au sein d'une rainure 16 correspondante, jusqu'à ce que l'extrémité arrière de la prothèse 2 vienne en butée contre l'extrémité du manche 24 adjacente aux languettes 28.

Une fois montée de cette manière, la prothèse maintenue sous forme cylindrique a subi une diminution globale de ses dimensions transversales du fait de la compression, de plus en plus sensible en allant vers l'avant de la prothèse. Comme le montre en particulier la figure 6, la partie médiane 12 de la prothèse est en particulier soumise à des efforts tendant à diriger sa périphérie extérieure vers les languettes 28 de l'outil de pose.

L'ensemble composé de la prothèse comprimée et des languettes 28 de l'outil de pose présente une forme globalement cylindrique. Comme le montre la figure 7, le montage de la prothèse 2 s'effectue par vissage au moyen du manche 4 de l'outil de pose 22. Le filetage 14 dont est pourvue la surface extérieure des coiffes 6 est avantageux à l'égard de cette

opération.

La surface extérieure des languettes 28 est avantageusement lisse car l'outil de pose doit être retiré après montage.

La figure 8 illustre l'opération consistant à retirer l'outil de pose 22 de la prothèse 2. A cet effet, une fois que cette dernière est implantée en un emplacement approprié, on la maintient axialement au moyen de la tige 27 pénétrant dans l'orifice 26 ménagé dans le manche 24. Puis, on fait coulisser vers l'arrière les nervures 30 des languettes 28 le long des rainures 16 des coiffes 6. La prothèse recouvre alors sa forme originelle, telle que représentée aux figures 1 à 3, du fait de la nature de son matériau constitutif précontraint.

Les figures 5 à 8 illustrent l'implantation d'une prothèse 2 destinée à être placée à l'arrière de l'espace intervertébral et donc à constituer une prothèse partielle postérieure. On peut également prévoir que cette prothèse 2 soit positionnée à l'avant de cet espace intervertébral. A cet effet, il convient de solidariser, par rapport à l'outil de pose 22, cette prothèse en disposant sa partie antérieure évasée de manière adjacente au manche 24. La pose de cette prothèse est ensuite effectuée par vissage, comme dans l'exemple décrit en référence à la figure 7. Cette implantation est réalisée depuis la partie antérieure du patient, par exemple par coelioscopie.

La figure 9 représente une prothèse 102 conforme à un second mode de réalisation de l'invention. L'âme 104 de cette dernière comprend, de manière analogue à celle 4 décrite en référence aux figures précédentes, deux portions d'extrémité 108 dont la périphérie extérieure décrit un arc de cercle. Ces portions 108 sont reliées, non plus par des méplats, mais au moyen de gorges 136, de sorte que les portions d'extrémités 108 constituent des portions renflées reliées au moyen d'une partie médiane en forme de col 138. Chaque portion d'extrémité 108 est recouverte au moyen de coiffes 106 formant enrobage, dont l'une 106A s'étend longitudinalement au-delà de l'extrémité avant de l'âme 104, sur une longueur l. Cette coiffe 106A est destinée à constituer la coiffe supérieure, une fois la prothèse implantée. La coiffe supérieure 106A fait saillie par rapport à la partie avant de l'âme 104 d'environ quelques millimètres.

Les autres éléments constitutifs de cette prothèse 102 auxquels il n'est pas fait allusion dans la présente description, sont identiques à ceux de la prothèse 2 décrite précédemment.

5 La figure 10 représente une prothèse 202 conforme à un troisième mode de réalisation de l'invention.

Cette prothèse 202 comporte deux enrobages formés par des coiffes 206A et 206B respectivement supérieure et inférieure de dimensions axiales équivalentes.

10 La coiffe supérieure 206A fait saillie au-delà de l'extrémité avant de l'âme 204, de manière analogue à la prothèse 102.

Une butée 240 fait saillie à partir de la coiffe inférieure 206B en direction de la coiffe supérieure 206A. Les dimensions de cette butée sont telles qu'elle limite le mouvement d'inclinaison de la coiffe supérieure 206A à une valeur déterminée par rapport à un axe (A') parallèle à l'axe (A) de la coiffe inférieure. Par exemple, l'inclinaison maximale de la coiffe supérieure 206A peut être limitée à environ 5° (angle  $\alpha$ ) vers le bas, par rapport à l'axe (A').

20 La butée 240 est réalisée en un matériau analogue à celui constituant l'âme 204, et peut être venue de matière avec cette dernière. Les éléments non décrits de cette prothèse sont analogues à ceux de la prothèse 102.

On peut prévoir qu'un renforcement analogue à celui 20 soit ménagé dans la partie arrière de la prothèse conforme à l'invention. Toutefois, ce renforcement doit alors présenter des dimensions sensiblement inférieures au renforcement 20, de sorte qu'une flexion préférentielle est réalisée au niveau de la partie avant de la prothèse.

30 Les figures 11 à 13 représentent un quatrième mode de réalisation d'une prothèse discale partielle conforme à l'invention, désignée dans son ensemble par la référence 302. Cette prothèse comprend une âme 304 réalisée en un matériau élastique biocompatible, comme par exemple un polymère de silicone ou un caoutchouc pré-contraint, âme 304 dont la surface extérieure est partiellement recouverte au moyen de deux coiffes 306A, 306B formant enrobage. Ces dernières sont exécutées en un matériau rigide biocompatible tel que par

exemple un acier spécial, notamment du titane, et sont assujetties à l'âme 304 par exemple par une colle de silicone.

5 Comme le montrent en particulier les figures 12 et 13, la section de l'âme 304 se compose de deux portions d'extrémités 308 dont la périphérie extérieure décrit un arc de cercle, qui sont reliées par deux méplats 310 formant une partie médiane 312.

10 La dimension transversale ou largeur D des portions d'extrémités 308 est sensiblement constante tout le long de la prothèse 302 alors que la dimension ou hauteur H des méplats 310 reliant les portions d'extrémités augmente vers l'avant de la prothèse en faisant référence à celle-ci une fois implantée dans le corps d'un patient. L'âme 304 est pourvue d'un premier et d'un second renflements 314, 316, dénommés encore renflements 15 antérieur et postérieur. Il convient de noter que le renforcement antérieur 314 présente des dimensions axiales supérieures et un rayon de courbure inférieur à ceux du renforcement postérieur 316.

20 Ces renflements 314, 316 en forme de coupelle constituent des amorces de flexion, leurs dimensions respectives conférant un aspect privilégié à la flexion vers l'avant. Le renforcement antérieur 314 est prolongé, à l'une de ses extrémités, par une extension 318 de l'âme 304, de sorte que l'une des portions d'extrémités 308 possède des dimensions 25 longitudinales supérieures à celles lui faisant face.

La prothèse 302 est percée longitudinalement d'un orifice débouchant 318, destiné au passage d'une tige d'un outil de pose comme cela sera explicité dans ce qui suit.

30 Chaque coiffe 306 est réalisée sous forme d'un profilé présentant, en coupe transversale, une forme d'arc de cercle. Ces coiffes recouvrent la totalité de la périphérie extérieure des portions d'extrémités 308 de l'âme 304, alors que les méplats 310 ne sont pas recouverts. La surface extérieure de ces coiffes est munie d'un filetage 321 destiné à faciliter 35 l'implantation de la prothèse, comme cela sera explicité dans ce qui suit.

La surface extérieure des coiffes 306 possède des irrégularités formées par exemple par gaufrage ou frittage, qui sont

destinées à garantir une bonne stabilité de la prothèse une fois implantée. Les coiffes 306 sont pourvues, à leur extrémité antérieure, de rabats 322 respectifs faisant saillie l'un vers l'autre, de manière à se chevaucher partiellement à l'état libre de la prothèse. Du fait de l'extension 318, l'un 322A de ces rabats est plus éloigné de l'extrémité postérieure de la prothèse que l'autre rabat 322B. Dans un souci de clarté, ces rabats 322A, 322B seront donc dénommés respectivement distal et proximal.

Chacun de ces rabats est pourvu d'une ouverture respective 324A, 324B de section sensiblement circulaire. L'emplacement de ces ouvertures est tel que ces dernières sont mutuellement alignées selon la direction longitudinale de la prothèse et sont co-axiales à l'orifice 320, lorsque la prothèse se trouve dans un état transversalement comprimé, comme cela sera décrit en particulier à la référence à la figure 15. La coiffe munie du rabat distal 322B est terminée par une saillie 326 s'étendant au-delà de ce rabat, à l'opposé de l'âme 304. Cette saillie 326 constitue une butée pour le rabat distal 322A, de manière à limiter le mouvement de flexion global de la partie antérieure de la prothèse.

La figure 14 représente un outil, désigné dans son ensemble par la référence 328, destiné à la pose de la prothèse représentée aux figures 11 à 14.

Cet outil 328 comprend des premier et second éléments amovibles 330, 332. Le premier élément 330 se compose d'un fût cylindrique 334 assumant une fonction de manche de préhension, terminé par deux languettes 336 à section transversale en forme d'arc de cercle, destinées à prendre appui contre les bordures des coiffes de la prothèse comme cela sera décrit dans ce qui suit. Le fût 334 est creux et annulaire et comprend un logement axial cylindrique 338.

Le second élément 332 est constitué par une tige 340 cylindrique terminée par une extrémité amincie 342 destinée à former clavette, dont la fonction sera explicitée en particulier en référence aux figures 16 et 17. La dimension transversale principale, ou largeur l, de cette extrémité 342 décroît à l'opposé de la tige 340. La tige 340 est prolongée, à

l'opposé de son extrémité 342, par une portion cylindrique élargie 344, d'adaptation dans le logement 338 du fût 334. La portion d'adaptation 344 est elle-même terminée par une poignée 346. La tige 340 et la portion d'adaptation 344 sont libres de coulisser par rapport au fût 334 et de pivoter autour de l'axe principal de ce dernier.

La figure 15 illustre l'assujettissement mutuel de l'outil de pose 328 et de la prothèse 302. A cet effet, il convient tout d'abord d'insérer la tige 340 puis la portion d'adaptation 10 344 dans le logement annulaire 338. Puis, il s'agit de comprimer la prothèse 302, de sorte que cette dernière présente une section transversale globalement cylindrique. Une telle mise en compression peut être assurée par exemple manuellement ou au moyen d'une pince appropriée.

15 On introduit ensuite la tige 340, par son extrémité amincie 342, au travers de l'orifice 320 puis au sein des deux ouvertures 324A, 324B disposées dans le prolongement l'une de l'autre. L'insertion de cette tige 340 assure alors la solidarisation de la prothèse 302 et de l'outil de pose 328 dans 20 l'état transversalement comprimé de la prothèse. En même temps que l'on a inséré la tige 340 dans les ouvertures 324A, 324B, on a déplacé longitudinalement le fût 334, de manière que les languettes 336 prennent appui contre les bordures de chaque coiffe 306A, 306B, de façon à former, avec la surface extérieure de la prothèse, une surface globalement cylindrique.

25 L'implantation de la prothèse dans le corps du patient s'effectue par vissage au moyen d'une action exercée sur le fût 334 formant manche. Les filetages 321 dont est pourvu la périphérie extérieure des coiffes 306 sont avantageux à l'égard de cette opération. Une fois la prothèse en place, on exerce un effort longitudinal tendant à retirer la tige 340 des ouvertures 324A, 324B, de sorte que la prothèse retrouve une configuration évasée vers sa partie antérieure, du fait de la nature de son matériau constitutif précontraint. On retire ensuite les 30 languettes 336 par coulissemement.

35 La figure 16 représente le positionnement mutuel des rabats 322A, 322B, une fois que la prothèse 302 a été implantée dans le corps du patient. La prothèse se trouve alors dans un

état de compression intermédiaire entre son état libre représenté en référence aux figures 11 à 13 et son état comprimé en vue de la pose, représenté à la figure 15.

En effet, les vertèbres entre lesquelles elle est disposée exercent sur cette prothèse une certaine force, qui est toutefois inférieure à celle à laquelle elle est soumise durant sa pose. Il existe donc, vue en bout, une zone de recouvrement Z entre les ouvertures 324A, 324B dont sont munis les rabats 322A, 322B. La présence de cette zone de recouvrement est particulièrement avantageuse dans le cas où l'on désire retirer la prothèse, notamment en cas de descellement ou d'infection.

A cet effet, on introduit la tige 340 et la portion d'adaptation 334 au sein du fût 344, puis l'on insère l'extrémité 342 de cette tige 340 au sein de cette zone de recouvrement Z. Etant donné que la largeur l de l'extrémité 342 croît en allant vers le tige 340, les parois latérales de cette extrémité 342 viennent en butée, lors de son introduction, contre le pourtour de la zone de recouvrement, comme le montre la figure 16. On effectue alors un quart de tour au moyen de la poignée 346 solidaire de la tige 340, de manière à rapprocher l'une de l'autre les ouvertures 324A, 324B, comme cela est représenté à la figure 17. La convergence de l'extrémité 342 permet à cette dernière de s'adapter à des zones de recouvrement de dimensions différentes.

Ensuite, on exerce un effort axial de poussée sur la tige 340 afin d'engager le corps cylindrique de la tige 340 au sein des ouvertures 324A, 324B. La prothèse se trouve alors dans le même état transversalement comprimé que lors de sa pose illustrée à la figure 15.

De manière analogue, on enfile les languettes 336 le long des bordures des coiffes 306. Il est alors possible de dévisser la prothèse 302, de manière à la retirer du corps du patient. La prothèse 302 illustrée aux figures 15 à 17 est une prothèse postérieure, étant donné que son implantation est effectuée depuis le dos du patient et qu'elle doit remplacer la partie postérieure du disque.

Cependant, une telle prothèse 302 peut également être implantée depuis la face antérieure du patient afin d'être

disposée à la partie antérieure, voire antéro-médiane de l'espace intervertébral. Cette implantation diffère de celle décrite ci-dessus uniquement en ce sens que, pour solidariser la tige 340 par rapport à la prothèse 302, il faut introduire 5 cette tige tout d'abord au travers des ouvertures 324A, 324B de la prothèse, puis au sein de l'orifice 320 de cette dernière.

La prothèse 302 a été représentée avec des portions d'extrémités 308 dont la dimension transversale est sensiblement constante tout le long de cette prothèse. On peut également prévoir que ces extrémités, tout en présentant un rayon de courbure sensiblement constant tout le long de cette prothèse, s'étendent selon un secteur angulaire qui augmente continûment vers la partie antérieure de la prothèse. 10

Les figures 18 à 22 représentent un cinquième mode de 15 réalisation d'une prothèse discale partielle conforme à l'invention, désignée dans son ensemble par la référence 402. Cette prothèse comprend une âme 404 réalisée en un matériau élastique bio-compatible et dont la surface extérieure est partiellement recouverte au moyen d'un enrobage formé de deux 20 éléments 406A et 406B. Ces derniers, exécutés en un matériau rigide bio-compatible, sont assujettis à l'âme 404 par exemple au moyen d'une colle de silicone.

La section transversale de l'âme 404 se compose de deux portions d'extrémité 408 dont la périphérie extérieure décrit 25 un arc de cercle et qui sont reliées par deux méplats 410 formant une partie médiane 412.

La dimension transversale ou largeur des portions d'extrémités 408 est sensiblement constante tout le long de la prothèse 402, alors que la hauteur des méplats 410 augmente 30 vers l'avant de la prothèse, en faisant référence à celle-ci une fois implantée.

Chaque enrobage 406 comprend une calotte centrale 414 destinée à entrer en contact avec l'âme 404. Cette calotte 414 est reliée à une coiffe périphérique 416 réalisée sous forme 35 d'un profilé présentant, en coupe transversale, une forme d'arc de cercle. La surface extérieure de ces coiffes est munie d'un filetage 418 destiné à faciliter l'implantation de la prothèse.

La zone de liaison entre la calotte 414 et la coiffe 416

comprend une bordure périphérique 420 s'étendant autour de la calotte et prolongée par deux pattes longitudinales 422. Ces dernières définissent, au voisinage de la bordure 420, deux glissières ou rainures longitudinales 424. Ces pattes 422 délimitent également, avec des volets d'extrémité 426, une échancrure traversante 428 en forme d'arc de cercle.

Il est prévu quatre volets, à savoir des volets avant 426A et arrière 426B pour l'enrobage 406A, et des volets avant 427A et arrière 427B pour l'enrobage 406B.

Chaque volet 426, 427 s'étend d'un des enrobages 406 vers celui qui lui est opposé, de manière sensiblement perpendiculaire à l'axe principal de la prothèse. Ces volets sont disposés de manière asymétrique.

Le volet avant 426A du premier enrobage 406A et le volet opposé, à savoir le volet arrière 427B de l'autre enrobage 406B s'étendent, selon leurs dimensions principales, de façon à former une zone de recouvrement ZR. Cette dernière est particulièrement visible à la figure 21. Les projections, sur un même plan, selon l'axe principal A de la prothèse, des volets 426A et 427B possèdent une région commune, qui forme la zone de recouvrement ZR. La présence de cette dernière est de nature à réduire le cisaillement antéro-postérieur auquel est soumise la prothèse 402 une fois implantée.

Comme le montre la figure 19, chaque volet 426, 427 s'étend, dans la position de repos non comprimée de la prothèse, à distance de la paroi en regard de l'âme 404. Ceci contribue à former des volumes différentiels longitudinaux, respectivement avant 430 et arrière 432, qui limitent l'expansion de la prothèse lors de sa compression.

Ceci est plus particulièrement représenté à la figure 20, qui illustre la position de compression maximale de la prothèse. Dans cette position, les parois de l'âme 404, qui étaient distantes des volets 426 dans la position de repos, prennent appui contre la face intérieure de ces volets. Dans cette position comprimée, les volets en regard, à savoir d'une part 426A, 427A, et d'autre part 426B, 427B sont distants l'un de l'autre.

Chaque enrobage 406 est également pourvu de jupes latéra-

les 434 s'étendant à partir de la bordure périphérique 420, entre chaque glissière 424 et la calotte 414. Comme le montre en particulier la figure 19, chaque jupe 434 présente, vue de côté, une hauteur variable, à savoir qu'elle s'étend selon un profil ondulé globalement sinusoïdal. Cependant, chaque jupe peut également comporter au moins un décrochement. Les jupes adjacentes, dont sont pourvus deux enrobages différents, présentent des profils sensiblement conjugués. Ainsi, les jupes 434A et 434C d'une part, ainsi que les jupes 434B et 434D d'autre part sont propres à venir en imbrication mutuelle.

En revanche, deux jupes en regard, c'est-à-dire soit 434A et 434B, soit 434C et 434D, sont disposées de façon asymétrique. Il existe donc des zones de recouvrement ZR', d'une part entre les jupes opposées 434A et 434D, d'autre part entre les jupes opposées 434B et 434C. Les projections sur un même plan, selon un axe perpendiculaire à l'axe principal de la prothèse, de chaque couple de jupes opposées, possèdent des régions communes qui forment ces zones de recouvrement. Ces dernières contribuent à réduire les effets de cisaillement latéral auquel est soumise la prothèse.

En coupe transversale, comme le montre en particulier la figure 21, chaque jupe 434 s'étend à distance des méplats 410 de l'âme 404. Ceci contribue à créer, de part et d'autre de l'âme 404, deux volumes différentiels latéraux 436. Lors de la compression maximale de la prothèse, représentée à la figure 22, l'âme 404 occupe l'ensemble de ces volumes différentiels 436, de manière à venir en contact avec la face intérieure des jupes 434. Dans cette position comprimée, il est à noter que les extrémités des jupes adjacentes, d'une part 434A et 434C, d'autre part 434B et 434D, s'étendent à distance l'une de l'autre.

La pose de la prothèse illustrée aux figures 18 à 23 s'effectue au moyen d'un outil sensiblement analogue à celui 22 décrit aux figures 4 à 8. Les glissières adjacentes, à savoir d'une part 424A et 424C, d'autre part 424B, 424D, permettent l'engagement de languettes analogues à celles 28 des figures 4 à 8. L'outil est également pourvu de languettes supplémentaires, non représentées sur ces figures 4 à 8, pénétrant dans les

deux échancrures 428 dont sont pourvus les enrobages 406. Le montage de la prothèse 402 est globalement analogue à celui de la prothèse 2, illustré en référence aux figures 1 à 8.

La figure 23 illustre une âme, désignée dans son ensemble par la référence 504, susceptible de remplacer l'âme d'une prothèse décrite précédemment. Cette âme 504 est composite, à savoir qu'elle comprend un noyau 504' entouré par une enveloppe 504'', le matériau constitutif du noyau 504' étant plus compressible que celui constitutif de l'enveloppe 504''. A titre d'exemple non limitatif, le noyau est réalisé en un polymère de silicium alors que l'enveloppe 504'' est constituée de polyéthylène ou de polyuréthane.

Ce noyau 504' occupe une partie substantielle du volume de l'âme 504, et se trouve entouré par l'enveloppe sur l'ensemble de la périphérie. On peut prévoir que le noyau réalisé en un matériau compressible soit séparé de l'enveloppe externe par une succession d'habillages intermédiaires, dont les matériaux constitutifs possèdent des caractéristiques de compressibilité alternées.

On peut également prévoir de réaliser l'âme sous forme d'un noyau en un matériau plus compressible, entourée d'une enveloppe en un matériau moins compressible. Ce noyau s'étendra alors uniquement à la partie arrière de la prothèse, dont les dimensions transversales sont réduites.

L'utilisation d'une âme composite est avantageuse en ce sens qu'elle limite l'expansion de cette âme et évite le phénomène de hernies.

La figure 24 illustre un mode de réalisation supplémentaire, dans laquelle l'âme 604 comprend plusieurs éléments distincts, à savoir un élément avant 604' de plus grandes dimensions transversales, et un élément arrière 604'' de dimensions transversales restreintes. Les termes "avant" et "arrière" sont relatifs à la prothèse une fois implantée. L'élément avant 604' est réalisé en un matériau plus compressible que l'élément arrière 604''. Chaque élément respectivement avant 604' et arrière 604'' comprend deux portions d'extrémité transversales 608', 608'' reliées par des portions médianes respectives 612', 612''.

Les deux portions d'extrémité d'un même élément sont disposées de façon globalement symétrique par rapport à un plan médian de la prothèse, qui correspond sensiblement au plan du disque intervertébral. Chaque portion d'extrémité 608', 608'' 5 est recouverte par un enrobage formant coiffe filetée 606, dont la paroi intérieure est conformée de manière à maintenir en place les éléments avant et arrière. On peut munir cette prothèse d'un enrobage analogue à celui recouvrant la prothèse des figures 18 à 22.

La prothèse conforme à l'invention permet de réaliser les objectifs précédemment mentionnés. En effet, la conformation en arc de cercle de ses portions d'extrémité, ainsi que la présence de coiffes rigides pourvues d'un filetage extérieur, assure une implantation aisée par vissage. Le fait que la prothèse présente des dimensions transversales plus importantes au niveau de sa partie avant qu'au niveau de sa partie arrière, lui confère un aspect lordosé qui se révèle avantageux d'un point de vue physiologique. La présence d'un renforcement au niveau de la partie avant, voire de la partie arrière de la prothèse, permet à celle-ci de voir ses dimensions transversales modifiées en fonction des efforts qu'elle subit, ce qui permet une grande liberté de mouvement au patient la recevant.

Les irrégularités de la surface extérieure des coiffes garantissent une bonne stabilité de la prothèse, à la fois par frottement sur les vertèbres et du fait de la repousse osseuse qui est susceptible d'y survenir.

Le fait qu'une coiffe s'étend au-delà de l'extrémité antérieure de l'âme (figure 9) conduit à la formation d'un bras de levier qui, associé à la présence des renflements, assure une flexion particulièrement aisée de cette partie antérieure de la prothèse.

La présence d'une butée limitant le mouvement de la coiffe supérieure réduit en outre les risques d'expulsion postérieure 35 de la prothèse.

La pose des prothèses représentées sur l'ensemble des figures est particulièrement aisée. En effet, étant donné que la prothèse est à même de subir une diminution sensible de ses

dimensions transversales, elle est propre à être implantée aisément, sans endommager les organes au voisinage desquels elle est déplacée. De plus, la solidarisation et la désolidarisation mutuelles de la prothèse et de l'outil de pose, qui sont assurées par coulissemement longitudinal, permettent un engagement aisé de la prothèse par rapport à l'outil de pose. Ce mode d'assujettissement garantit également la faculté de retirer facilement l'outil de pose de la prothèse, une fois cette dernière implantée. Etant donné que l'on retire l'outil de pose de manière longitudinale, il n'existe donc que de faibles risques d'endommager les organes au voisinage desquels on déplace cet outil.

La présence de rabats dans lesquels sont ménagées des ouvertures présentant, une fois la prothèse implantée, une zone de recouvrement, est particulièrement avantageuse. En effet, cette zone de recouvrement permet, grâce à l'insertion de l'extrémité formant clavette de la tige (figure 17), de comprimer la prothèse quand bien même l'accès direct à cette dernière est impossible pour le chirurgien. Cette mesure assure donc la possibilité de retirer la prothèse sans porter atteinte à l'intégrité physique du patient.

L'emploi de volets et/ou de jupes définissant, avec des parois en regard de l'âme, un volume différentiel d'expansion de l'âme est également avantageux. Ceci permet de conférer trois plages de compression différentes à la prothèse de l'invention. Dans une première plage, dite de charge faible, la prothèse ne se déforme sensiblement pas. Dans une deuxième plage, dite de charge moyenne, l'âme élastique se déforme de manière à occuper l'ensemble de ces volumes différentiels. Enfin, dans une troisième plage, dite de charge élevée, la prothèse est sensiblement rigide, étant donné que l'âme entre en contact, sans pouvoir être substantiellement déformée, contre les parois des jupes et/ou volets définissant ces volumes différentiels.

REVENDICATIONS

1. Prothèse discale partielle (2 ; 102 ; 202 ; 302 ; 402 ;  
5 602) destinée à être insérée entre deux vertèbres voisines, du  
type comprenant une âme (4 ; 104 ; 204 ; 304 ; 404 ; 504 ; 604)  
réalisée en un matériau élastique tel qu'un polymère de  
silicone ou un élastomère, recouverte, sur une partie de sa  
périmétrie, par un enrobage (6 ; 106 ; 206 ; 306 ; 406 ; 606)  
10 réalisé en un matériau rigide et destiné à être en contact avec  
lesdites deux vertèbres voisines, caractérisée en ce que ladite  
âme comprend, en coupe transversale, deux portions d'extrémité  
(8 ; 108 ; 308 ; 408 ; 608', 608''), reliées par une portion  
15 médiane (12 ; 138 ; 312 ; 412 ; 612', 612''), ledit enrobage  
comprend deux coiffes (6 ; 106 ; 206 ; 306 ; 416 ; 606)  
pourvues d'un filetage et recouvrant respectivement au moins  
partiellement la périphérie externe desdites portions d'extré-  
mité (8 ; 108 ; 308 ; 408 ; 608', 608''), et la distance  
20 séparant lesdites coiffes augmente vers la partie antérieure de  
la prothèse.

2. Prothèse suivant la revendication 1, caractérisée en ce  
que l'âme (4 ; 104 ; 204 ; 304 ; 404 ; 504) est réalisée de  
façon monobloc et possède une forme allongée.

3. Prothèse suivant l'une des revendications 1 ou 2,  
25 caractérisée en ce que lesdites portions d'extrémité (8 ; 108 ;  
308 ; 408 ; 608', 608'') sont sensiblement en arc de cercle.

4. Prothèse suivant la revendication 3, caractérisée en ce  
que la dimension transversale (D) des portions d'extrémité (8 ;  
108 ; 308 ; 408) en arc de cercle est sensiblement constante  
30 tout le long de la prothèse.

5. Prothèse suivant la revendication 3, caractérisée en ce  
que lesdites portions d'extrémité présentent un rayon de  
courbure sensiblement constant tout le long de la prothèse et  
s'étendent selon un secteur angulaire qui augmente continûment  
35 vers la partie antérieure de la prothèse.

6. Prothèse suivant l'une quelconque des revendications 2  
à 5, caractérisée en ce que la partie antérieure de l'âme (4 ;  
104) est évidée de manière à former un renforcement (20)

d'amorce de flexion.

7. Prothèse suivant l'une quelconque des revendications 2 à 6, caractérisée en ce que la partie postérieure de la prothèse est pourvue d'un second renforcement d'amorce de flexion, dont les dimensions axiales sont sensiblement inférieures à celles du premier renforcement (20).

8. Prothèse suivant l'une quelconque des revendications 2 à 7, caractérisée en ce que la partie médiane (12 ; 312 ; 412) comprend deux méplats (10 ; 310 ; 410) reliant les extrémités voisines des deux portions d'extrémité (8 ; 308 ; 408).

9. Prothèse suivant l'une quelconque des revendications 2 à 7, caractérisée en ce que la partie médiane (138) comprend deux gorges (136) reliant les extrémités voisines des deux portions d'extrémité (108).

10. Prothèse suivant l'une quelconque des revendications 2 ou 9, l'âme monobloc (504) comprend un noyau (504') réalisé en un premier matériau et une enveloppe (504'') réalisée en un second matériau moins compressible que le premier matériau.

11. Prothèse suivant la revendication 1, caractérisée en ce que l'âme (604) comprend plusieurs éléments (604', 604'').

12. Prothèse suivant la revendication 11, caractérisée en ce que l'âme (604) comprend un élément arrière (604'') et un élément avant (604') plus compressible que l'élément arrière et dont les dimensions transversales sont supérieures à celle de l'élément arrière.

13. Prothèse suivant l'une quelconque des revendications précédentes, caractérisée en ce qu'au moins l'une des coiffes (106A ; 206A ; 406A, 406B) s'étend au-delà de l'extrémité antérieure de la portion d'extrémité (108) qu'elle recouvre.

14. Prothèse suivant l'une quelconque des revendications précédentes, caractérisée en ce que les coiffes (6 ; 106 ; 416) sont pourvues, au voisinage de chacune de leurs bordures (18), de rainures longitudinales (16 ; 424) propres à être enfilées par coulissolement dans des nervures (30) correspondantes dont est muni un outil de pose.

15. Prothèse suivant l'une quelconque des revendications précédentes, caractérisée en ce qu'elle est pourvue d'une butée (240) faisant saillie, depuis le voisinage de l'extrémité avant

d'une première coiffe (206B), en direction d'une seconde coiffe (206A), ladite butée étant apte à limiter le mouvement de ladite seconde coiffe (206A) en direction de ladite première coiffe (206B);

5 16. Prothèse suivant la revendication 15, caractérisée en ce que ladite butée (240) limite le mouvement de ladite seconde coiffe (206A) selon un angle prédéterminé ( $\alpha$ ) par rapport à un axe (A') parallèle à l'axe (A) de ladite première coiffe (206B).

10 17. Prothèse suivant l'une quelconque des revendications précédentes, caractérisée en ce que ladite prothèse est pourvue de moyens (426, 427) de réduction du cisaillement antéro-postérieur.

15 18. Prothèse suivant la revendication 17, caractérisée en ce que les moyens de réduction du cisaillement antéro-postérieur comprennent au moins un volet avant (426A) et un volet arrière (427B), dont est pourvu l'enrobage (406), lesdits volets s'étendant au voisinage des extrémités respectivement avant et arrière de ladite âme (404) et possédant une zone de recouvrement (ZR).

20 19. Prothèse suivant la revendication 18, caractérisée en ce qu'au moins un desdits volets (426, 427) s'étend, au moins en partie, à distance d'une paroi d'extrémité correspondante de ladite âme, de manière à former au moins un volume différentiel (430, 432) longitudinal avec ladite âme (404).

25 20. Prothèse suivant l'une quelconque des revendications précédentes, caractérisée en ce que ladite prothèse est pourvue de moyens (434) de réduction du cisaillement latéral.

30 21. Prothèse suivant la revendication 20, caractérisée en ce que les moyens de réduction du cisaillement latéral comprennent au moins des première (434A, 434C) et seconde (434B, 434D) jupes latérales opposées, dont est pourvu l'enrobage (406), lesdites jupes (434) s'étendant au voisinage des parois latérales de ladite âme et possédant une zone de recouvrement (ZR').

35 22. Prothèse suivant la revendication 21, caractérisée en ce que lesdites jupes présentent, en vue de côté, un bord non rectiligne, en particulier un bord formant au moins une

ondulation ou au moins un décrochement.

23. Prothèse suivant l'une des revendications 21 ou 22, caractérisée en ce qu'au moins une desdites jupes (434) s'étend, au moins en partie, à distance d'une paroi latérale correspondante de ladite âme (404), de manière à former au moins un volume différentiel latéral (436) avec ladite âme.

5 24. Prothèse suivant l'une quelconque des revendications précédentes, caractérisée en ce que ledit enrobage (406) comprend une calotte (414) de contact avec l'âme (404), séparée desdites coiffes par une zone de liaison (420, 422) échancree.

10 25. Prothèse suivant l'une quelconque des revendications précédentes, caractérisée en ce que la prothèse est pourvue d'un orifice longitudinal (320) de passage d'une tige (340) d'un outil de pose (328).

15 26. Prothèse suivant la revendication 25, caractérisée en ce qu'elle est pourvue de moyens de recompression (322A, 322B, 324A, 324B), propres à la ramener dans un état transversalement comprimé après sa pose.

20 27. Prothèse suivant la revendication 26, caractérisée en ce que les moyens de recompression comprennent deux rabats (322A, 322B) décalés longitudinalement et faisant saillie l'un vers l'autre à partir du voisinage de la partie antérieure de chaque coiffe (306A, 306B), lesdits rabats étant pourvus d'ouvertures (324A, 324B) respectives de passage de la tige (340) de l'outil de pose (328), alignées longitudinalement dans l'état transversalement comprimé de la prothèse.

25 28. Prothèse suivant la revendication 27, caractérisée en ce que lesdites ouvertures (324A, 324B) des rabats (322A, 322B) sont sensiblement circulaires et il existe, lorsque la prothèse est insérée entre les deux vertèbres voisines, une zone de recouvrement (Z) entre ces deux ouvertures, ladite zone de recouvrement présentant un profil transversal globalement ovale et étant propre à recevoir une extrémité aplatie (342) de ladite tige (340) dudit outil de pose (328).

30 35 29. Outil de pose pour la prothèse suivant l'une quelconque des revendications précédentes, caractérisé en ce qu'il comprend un manche de préhension (24 ; 334) prolongé par des moyens (28, 30 ; 336 ; 340) propres à solidariser ladite

prothèse par rapport audit outil dans un état transversalement comprimé de ladite prothèse.

30. Outil de pose suivant la revendication 29, caractérisé en ce que lesdits moyens de solidarisation comprennent des moyens de fixation (30) par enfilement.

31. Outil de pose suivant la revendication 30, caractérisé en ce que lesdits moyens de fixation par enfilement comprennent des nervures (30) dont est pourvu l'outil de pose (22) ou la prothèse (2), coopérant avec des rainures (16) ménagées dans la prothèse ou l'outil de pose.

32. Outil de pose suivant la revendication 31, caractérisé en ce que ledit manche (24) est prolongé par deux languettes (28) à section en forme d'arc de cercle, dans le volume intérieur desquelles la prothèse (2) est destinée à être engagée, la surface extérieure des languettes (28) formant, avec la surface extérieure de la prothèse (2) une fois engagée, une surface globalement cylindrique.

33. Outil de pose suivant la revendication 29 pour la pose d'une prothèse selon l'une quelconque des revendications 25 à 28, caractérisé en ce que lesdits moyens de solidarisation comprennent une tige (340) propre à pénétrer dans l'orifice longitudinal (320) dont est pourvue la prothèse (302).

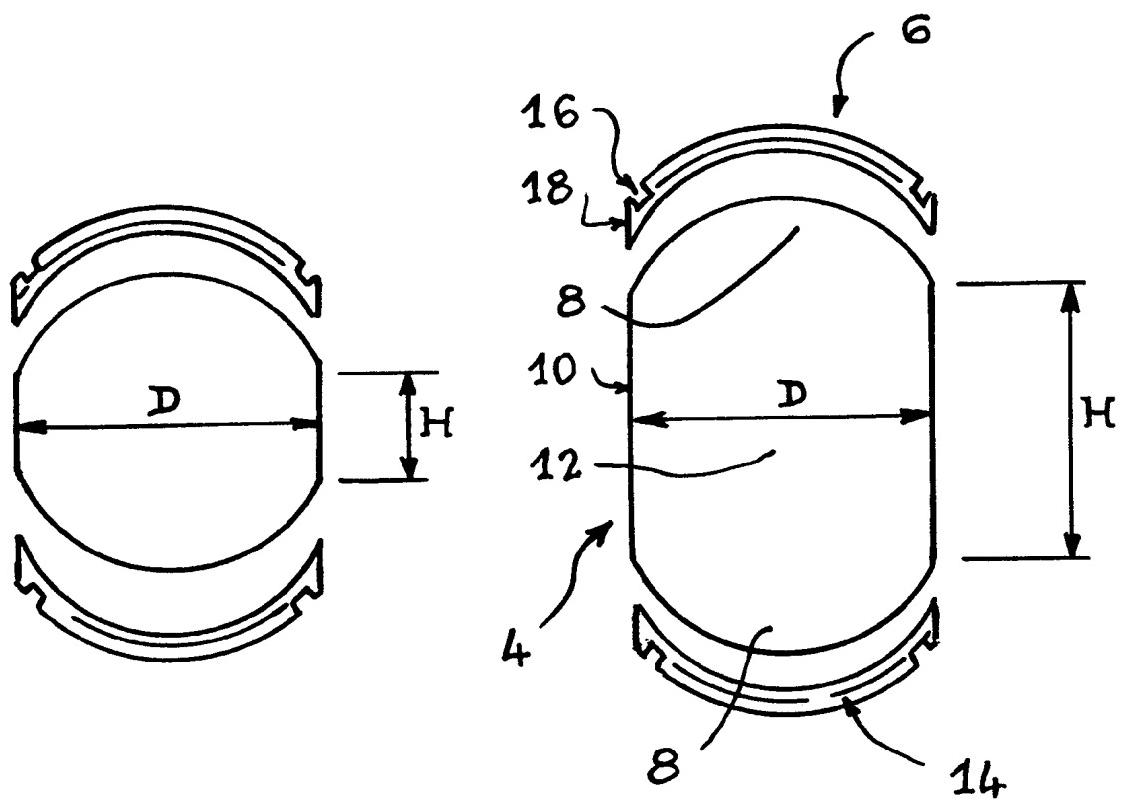
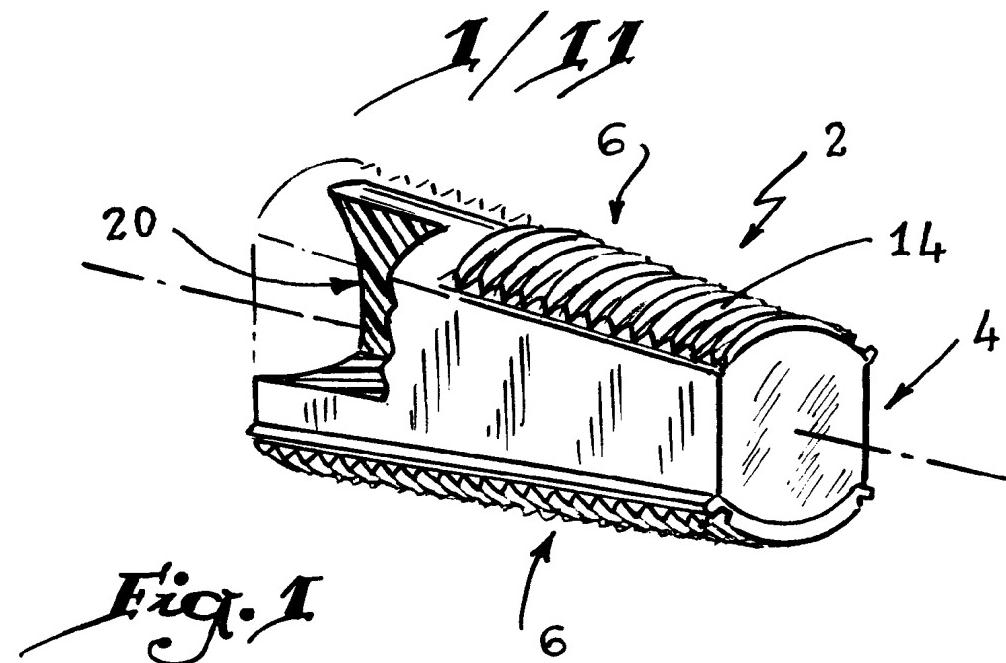
34. Outil de pose suivant la revendication 33, caractérisé en ce que la tige (340) est propre à pénétrer dans les ouvertures (324A, 324B) dont sont munis les rabats (322A, 322B).

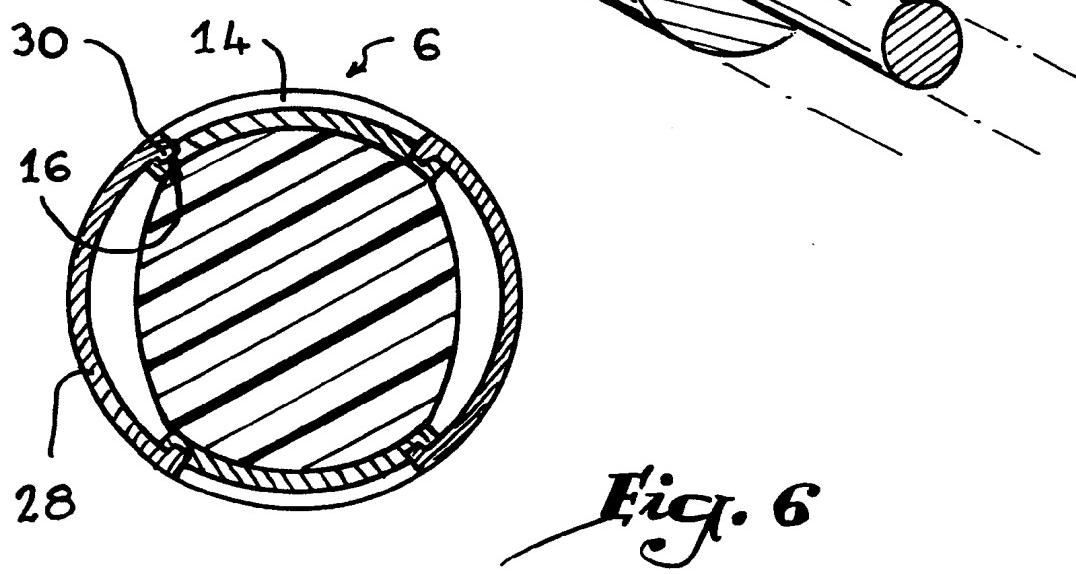
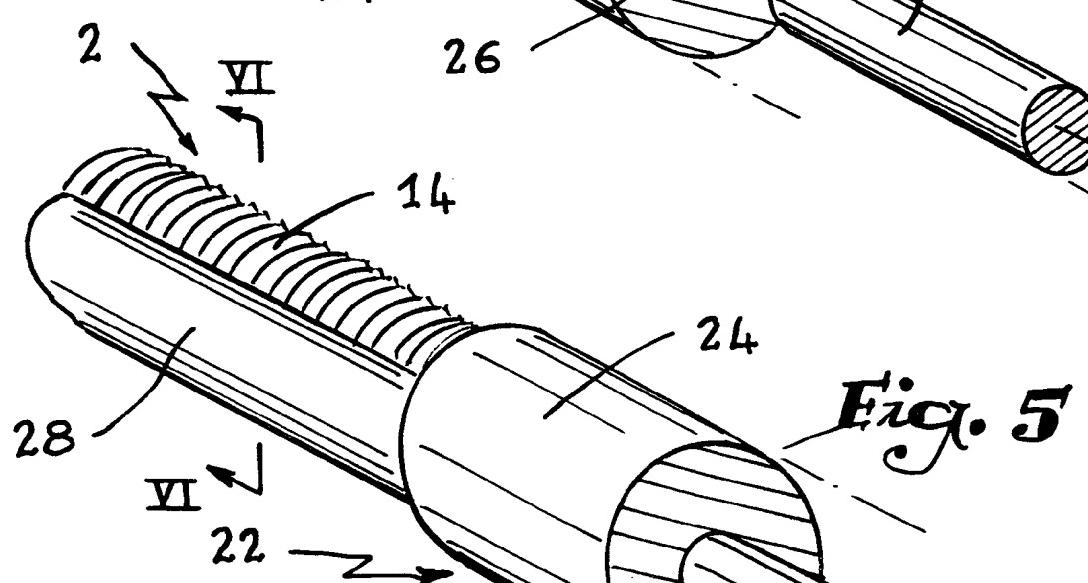
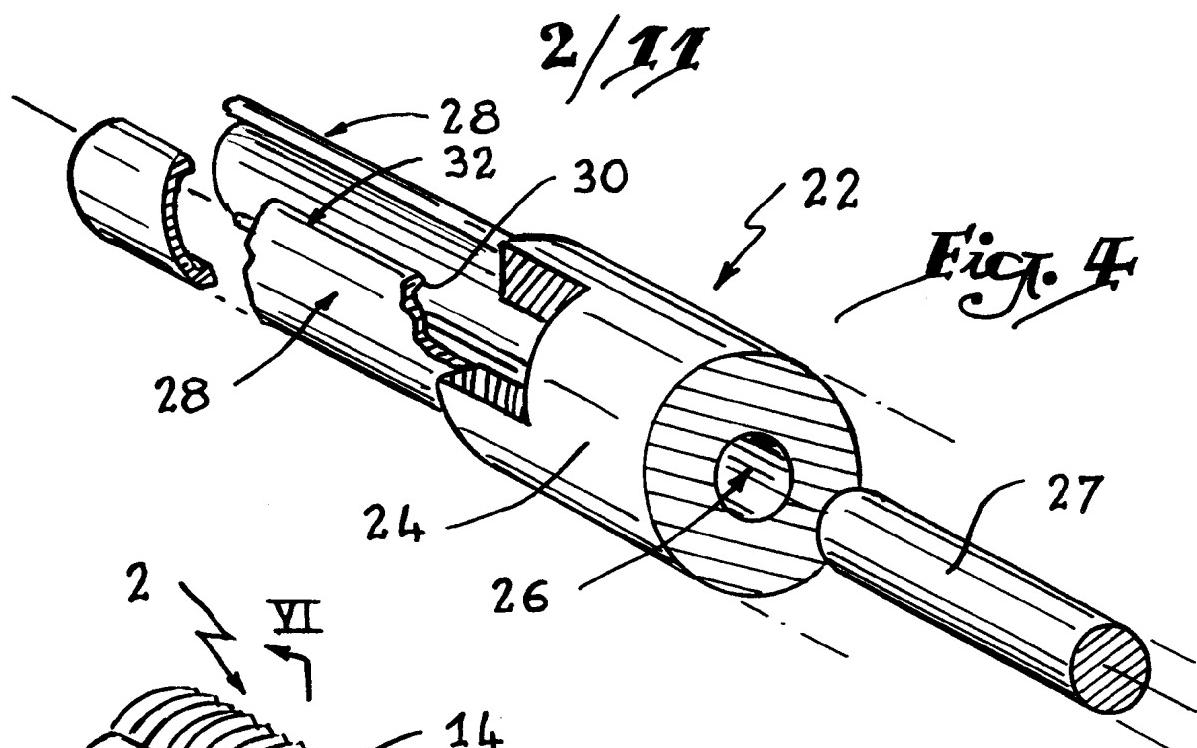
35. Outil de pose suivant la revendication 33 ou 34, caractérisé en ce que les moyens de solidarisation comprennent des languettes (336) à section en forme d'arc de cercle, dans le volume intérieur desquelles la prothèse (302) est destinée à être engagée, la surface extérieure des languettes (336) formant, avec la surface extérieure de la prothèse (302) une fois engagée, une surface globalement cylindrique.

36. Outil de pose suivant l'une des revendications 33 à 35, caractérisé en ce que ladite tige (340) est libre de pivoter par rapport audit manche (334).

37. Outil de pose suivant la revendication 36, caractérisé en ce que la tige (340) présente un profil transversal sensiblement circulaire et possède une extrémité distale aplatie

(342) qui est propre à pénétrer dans ladite zone de recouvrement (Z) entre les ouvertures (324A, 324B) desdits rabats (322A, 322B).





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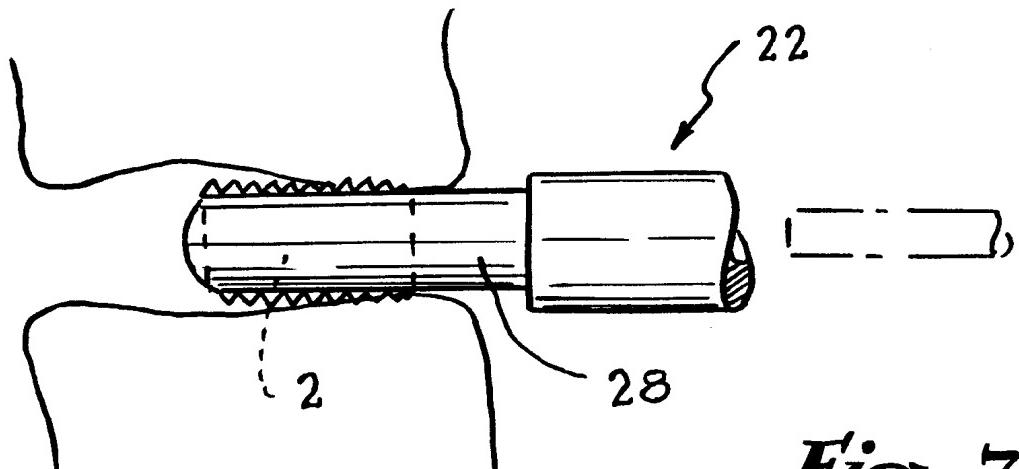


Fig. 7

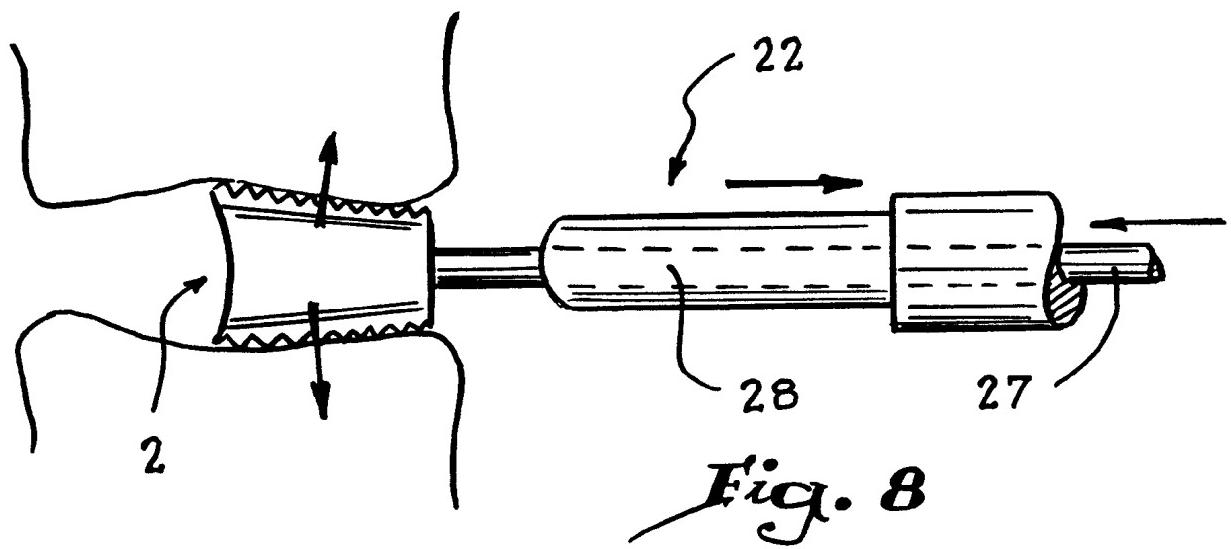


Fig. 8

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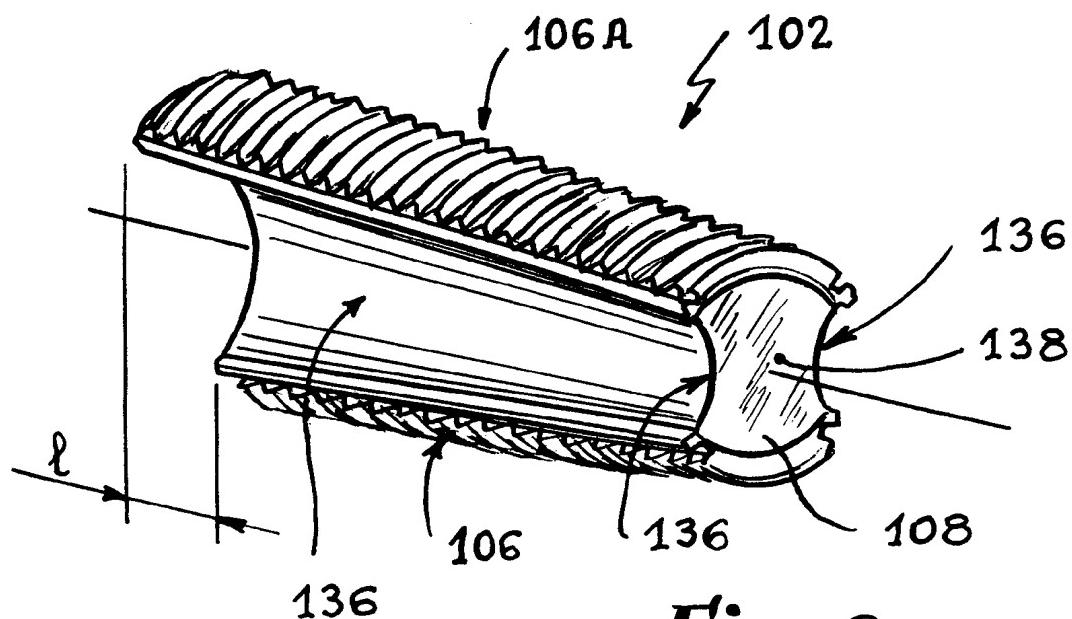


Fig. 9

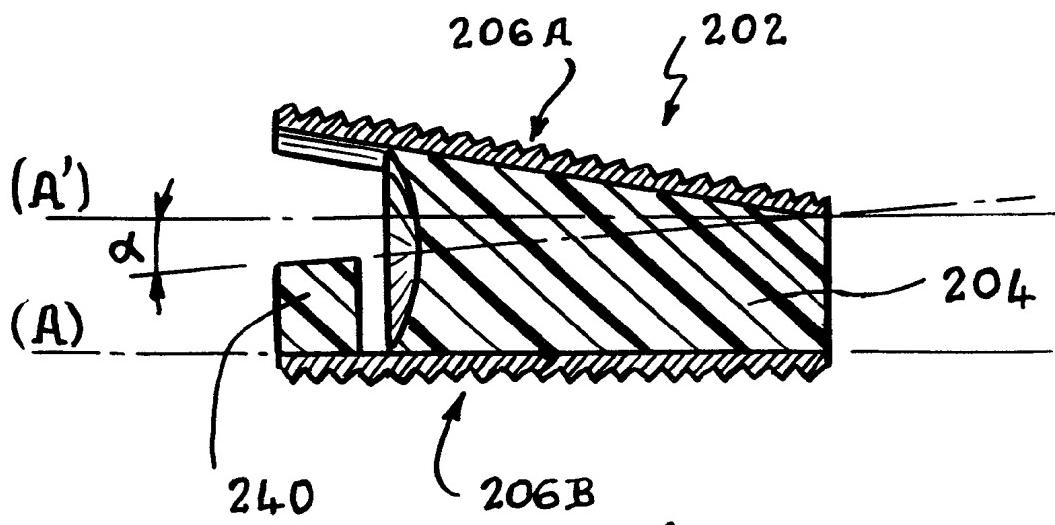


Fig. 10

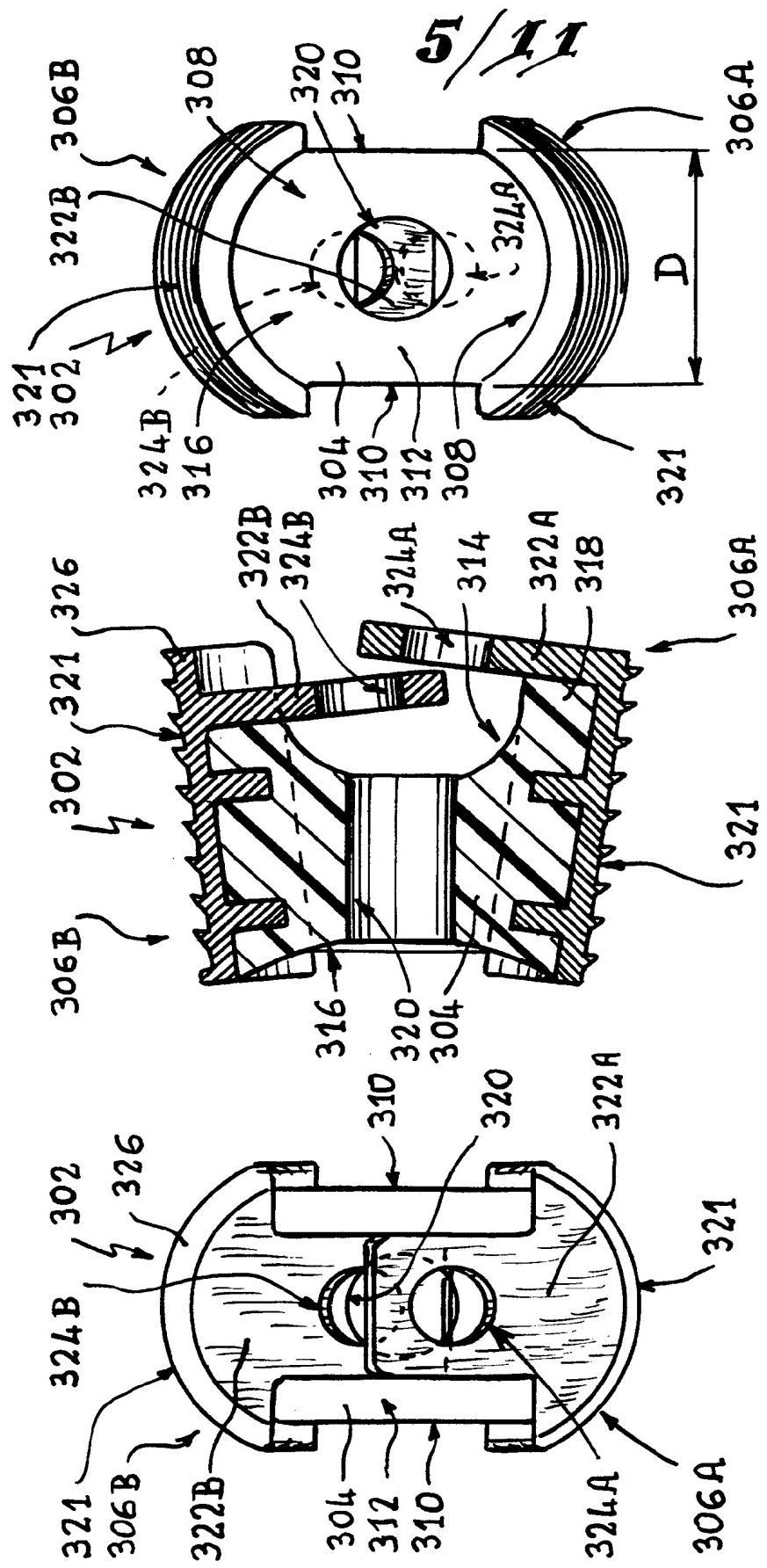
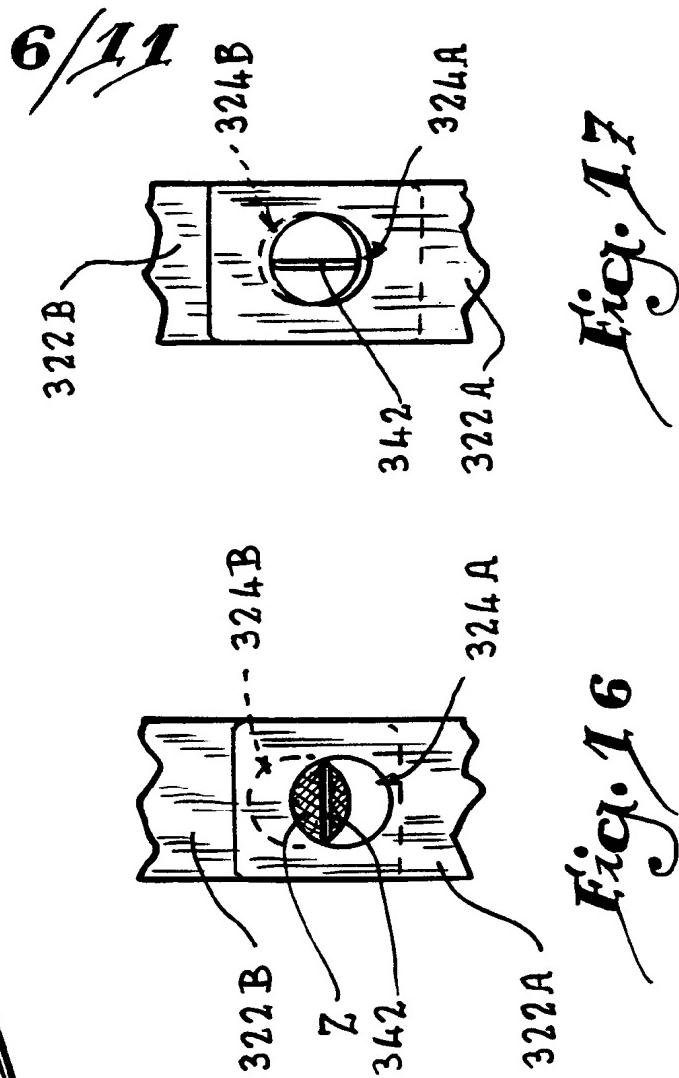
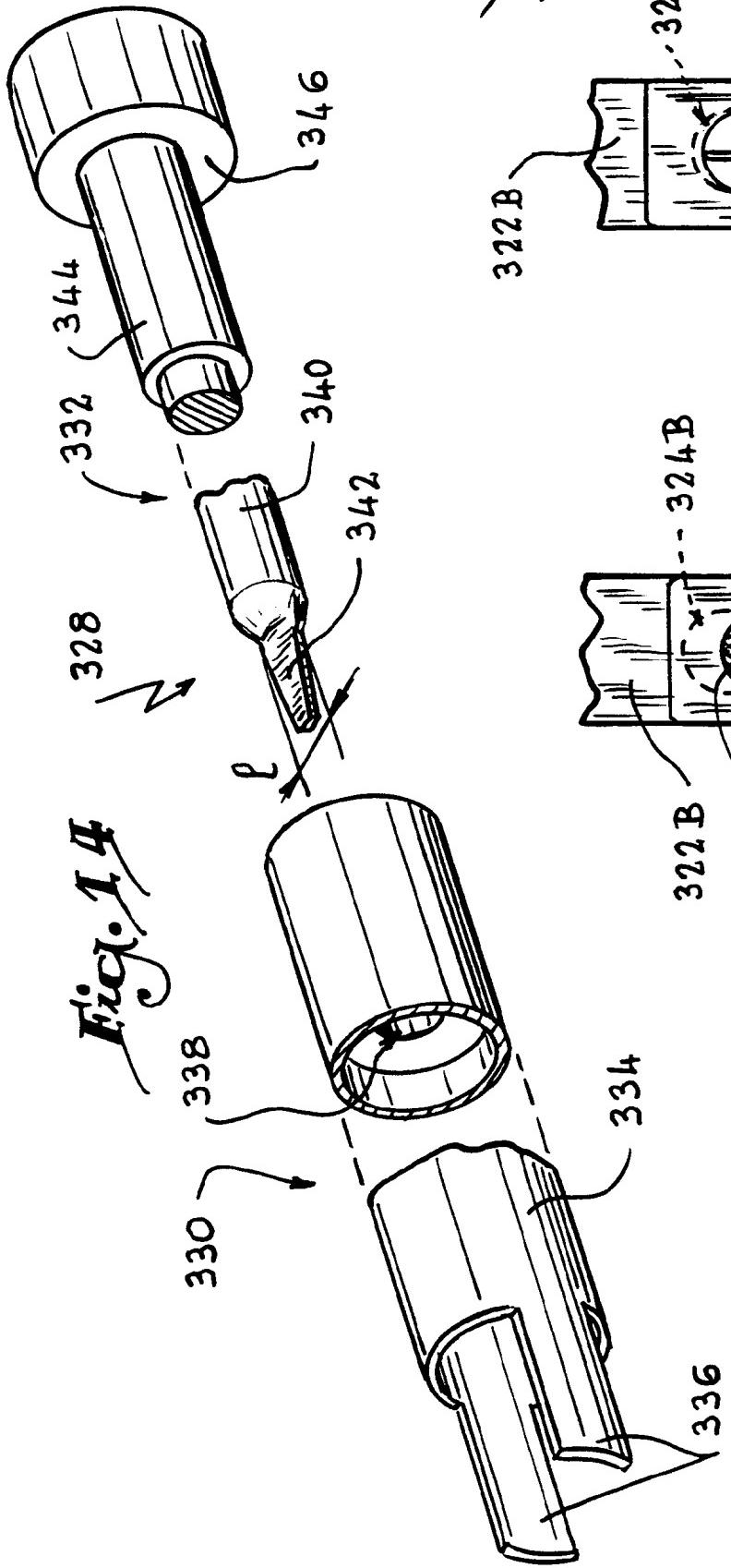


Fig. 12

*Fig. 11*

Fig. 13



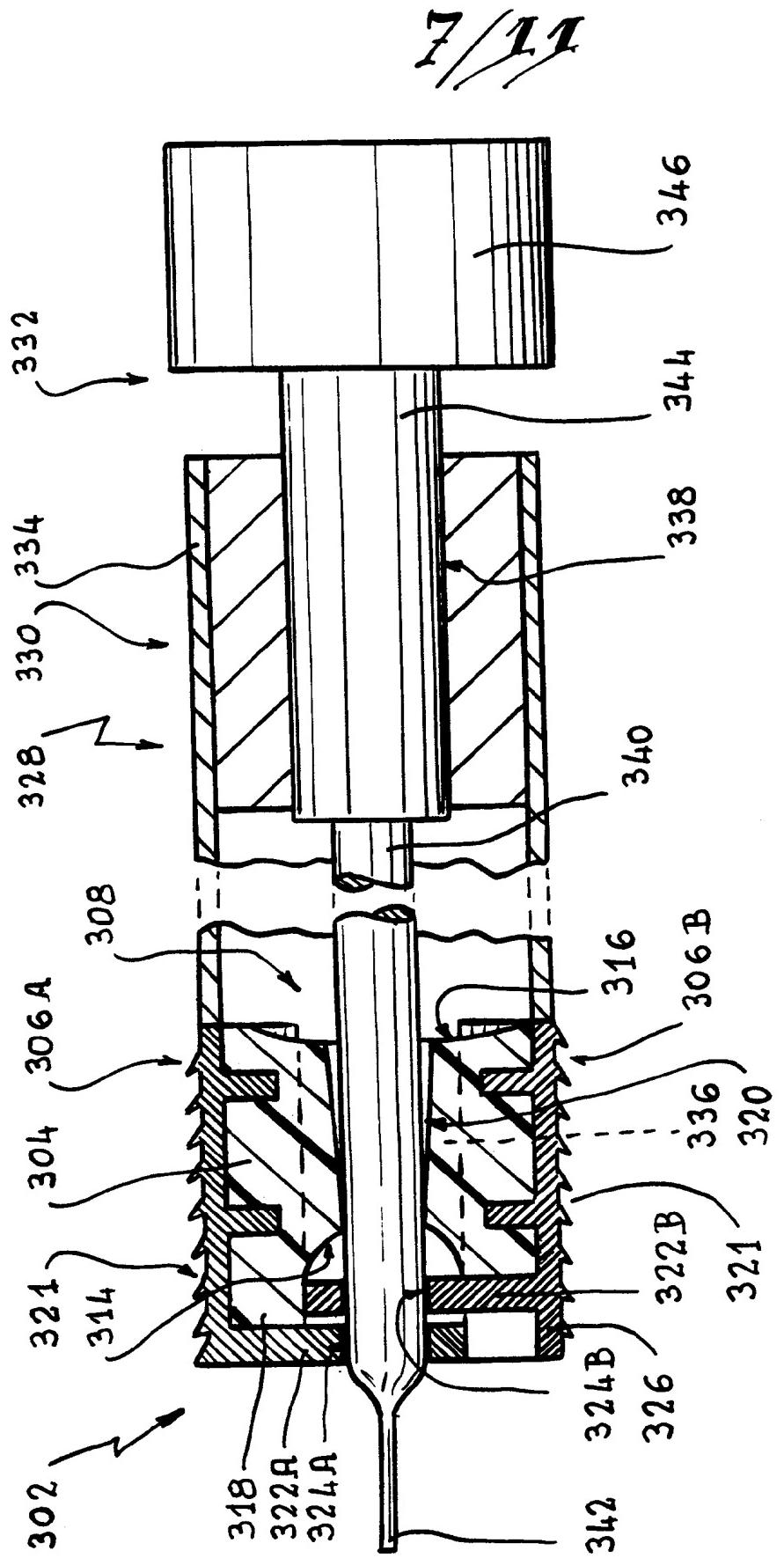


Fig. 15

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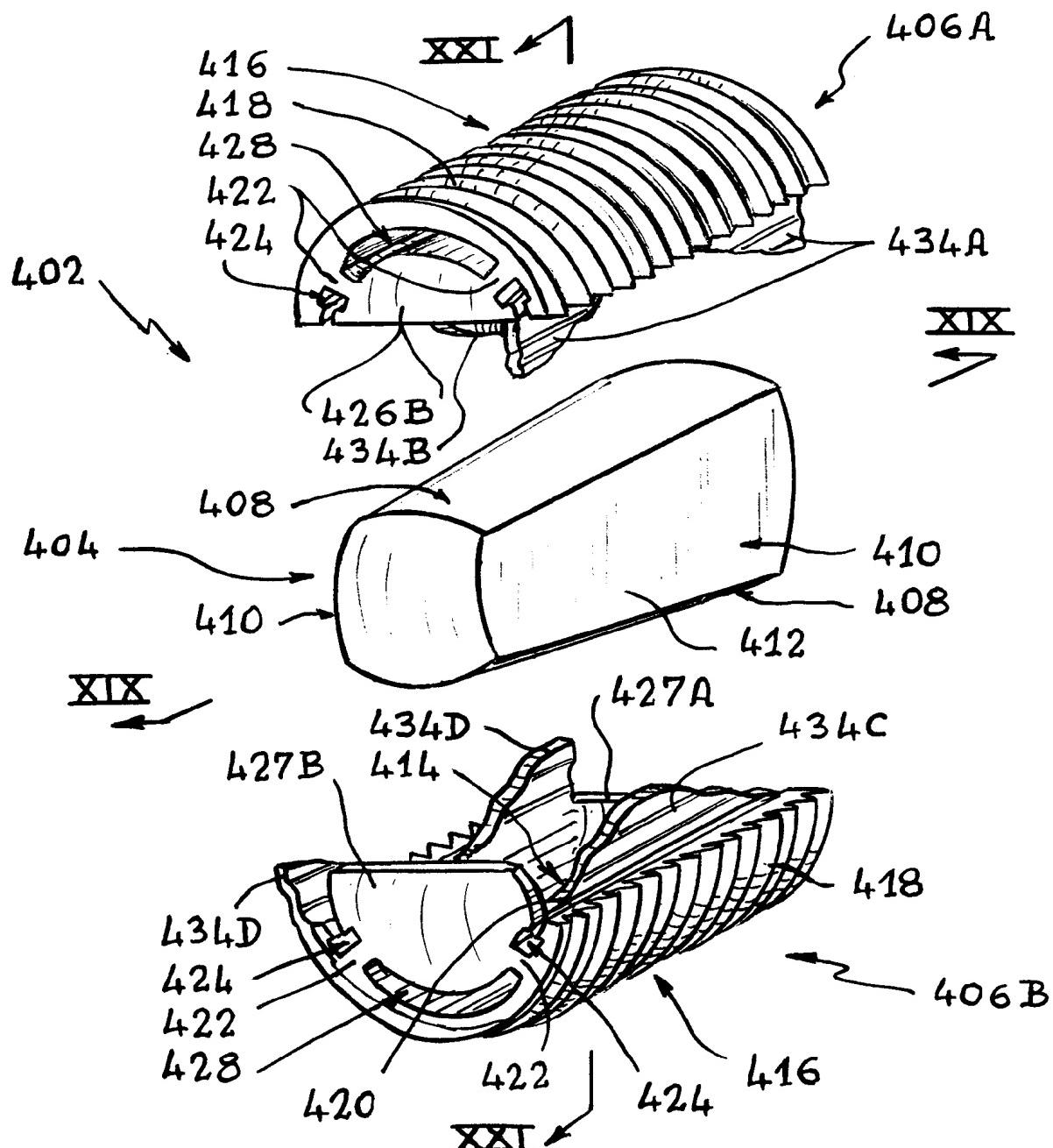
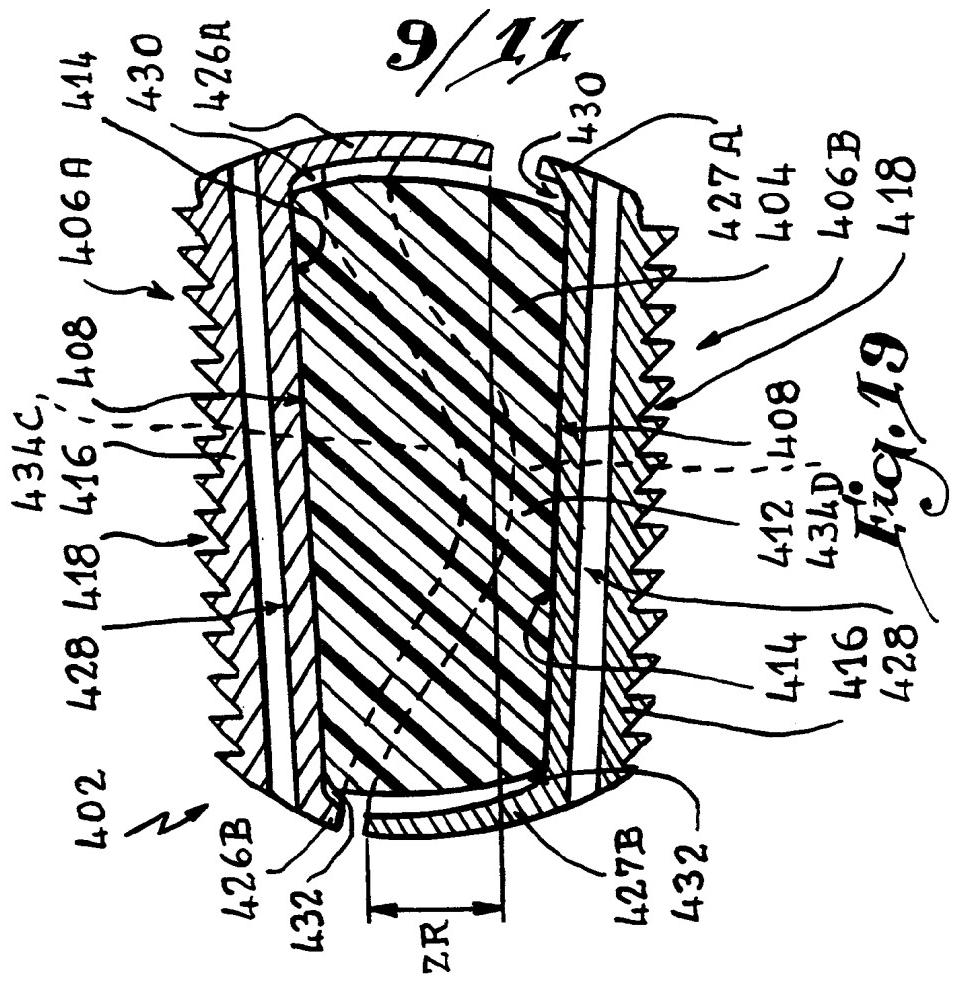
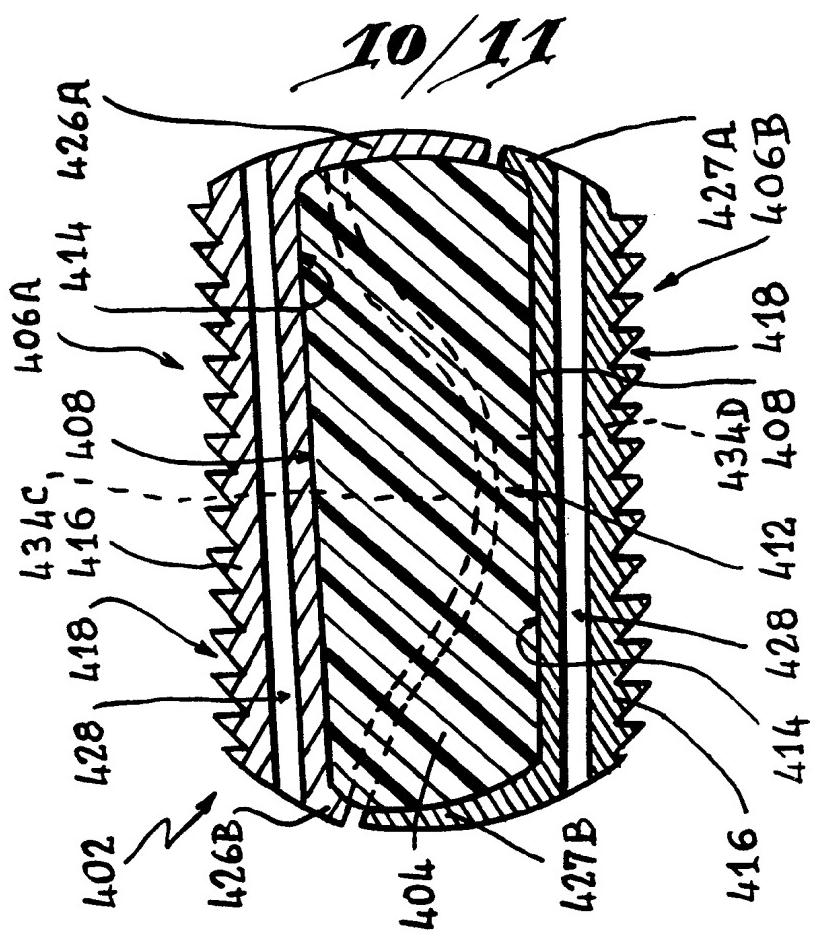


Fig. 18





*Fig. 20*

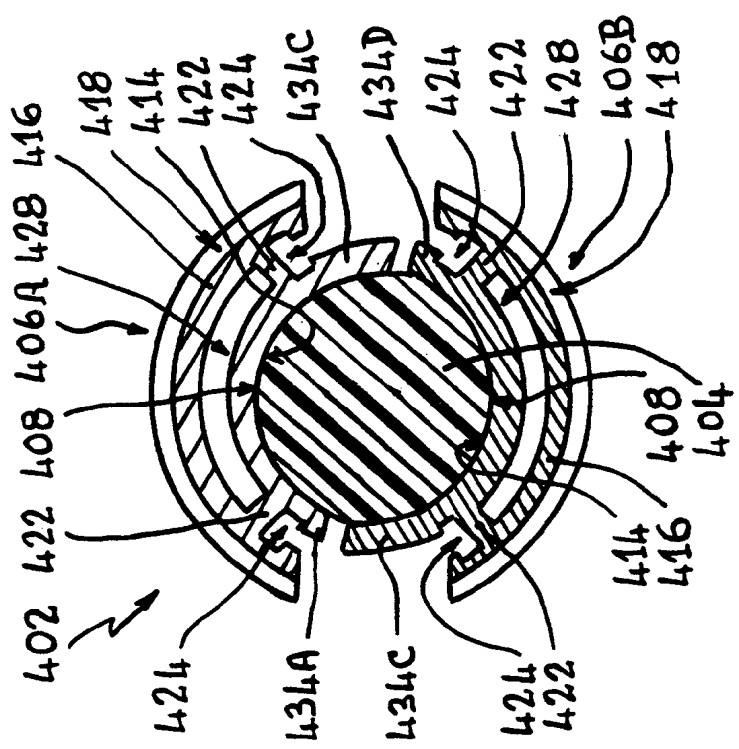
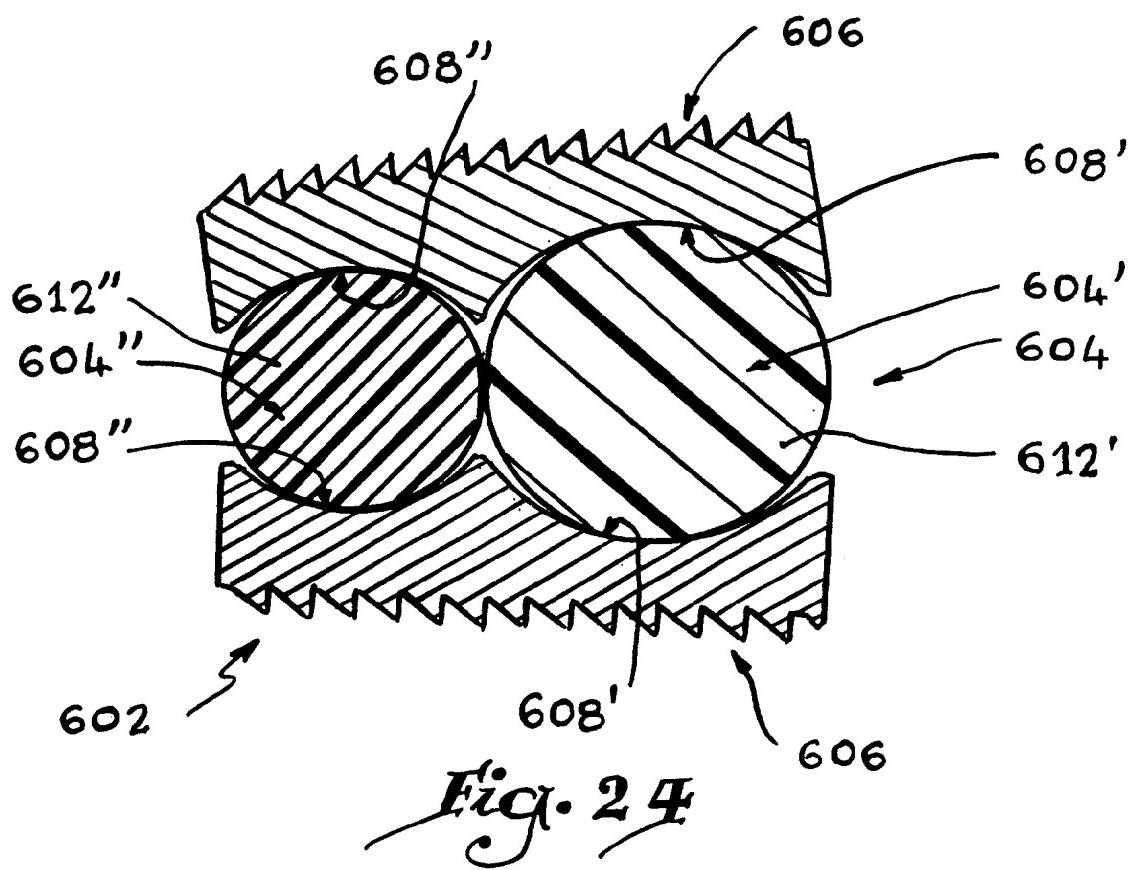
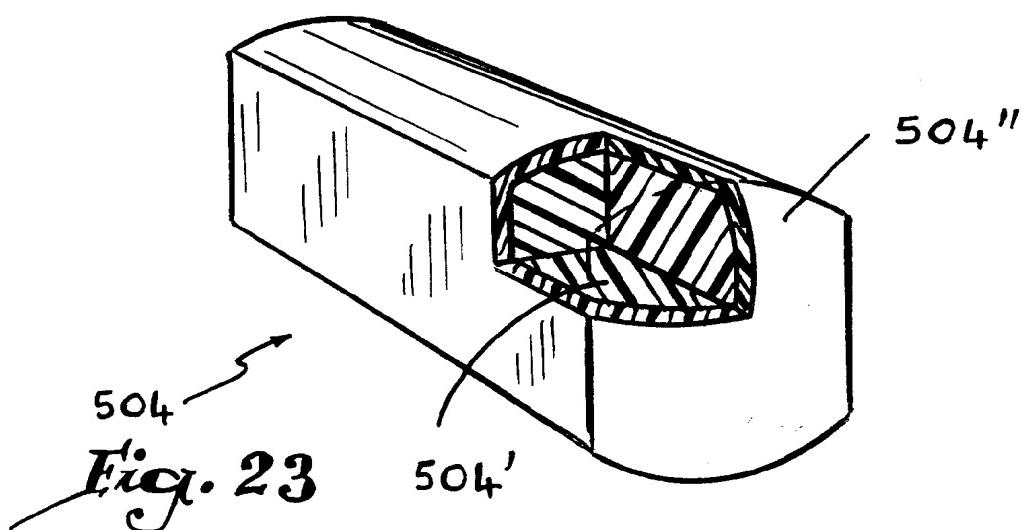


Fig. 22

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# INTERNATIONAL SEARCH REPORT

Inte. .onal Application No

PCT/FR 98/02798

**A. CLASSIFICATION OF SUBJECT MATTER**  
IPC 6 A61F2/44 A61F2/46

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 90 11740 A (BOSCH GMBH ROBERT) 18 October 1990	1
A	see the whole document ---	4,5,8
Y	WO 97 31517 A (DANEK MEDICAL INC) 28 August 1997	1
A	see the whole document ---	2-5,8,29
A	EP 0 260 044 A (SHEPPERD JOHN ANTHONY NORMAN) 16 March 1988 see column 4, line 29 - line 32; claim 1; figures ---	1-3,29
A	EP 0 566 810 A (SULZER MEDIZINALTECHNIK AG) 27 October 1993 see the whole document ---	1,6, 14-16 -/-

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1 April 1999

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09/04/1999

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A	US 5 616 142 A (YUAN HANSEN A ET AL) 1 April 1997 see figures 1,2,4C,5 ----	1,14
A	EP 0 610 837 A (ACROMED CORP) 17 August 1994 see figure 3 ----	1,9
A	WO 95 15133 A (CALCITEK INC) 8 June 1995  see the whole document ----	1,29,30, 32
A	WO 97 15247 A (BENOIT ALFRED ; KNOTHE INGA (CH); SYNTHES AG (CH); SYNTHES USA (US)) 1 May 1997 see page 5, last paragraph - page 6; claim 1; figures ----	1,29
A	EP 0 346 269 A (MECRON MED PROD GMBH) 13 December 1989 cited in the application ----	
A	DE 43 23 595 C (ESKA MEDICAL GMBH & CO) 7 July 1994 -----	

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Information on patent family members

International Application No

PCT/FR 98/02798

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# RAPPORT DE RECHERCHE INTERNATIONALE

Dem. Internationale No

PCT/FR 98/02798

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CIB 6 A61F2/44 A61F2/46

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Base de données électronique consultée au cours de la recherche internationale (nom de la base de données, et si réalisable, termes de recherche utilisés)

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Y	WO 90 11740 A (BOSCH GMBH ROBERT) 18 octobre 1990	1
A	voir le document en entier ----	4, 5, 8
Y	WO 97 31517 A (DANEK MEDICAL INC) 28 août 1997	1
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A	EP 0 566 810 A (SULZER MEDIZINALTECHNIK AG) 27 octobre 1993 voir le document en entier ----	1, 6, 14-16
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Fax: (+31-70) 340-3016

Fonctionnaire autorisé

Kanal, P

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Dem. à Internationale No

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A	WO 95 00082 A (BISSERIE MICHEL) 5 janvier 1995 voir le document en entier ---	1,13
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(54) Title:	SPACER ASSEMBLY FOR USE IN SPINAL SURGERIES		
(57) Abstract	<p>A spacer assembly (100) is provided for use in spinal surgeries. Spacer assembly (100) includes a spacer (12) having opposite ends (24, 26) and a side wall (30) extending between opposite ends (24, 26) and at least one end cap (10) coupled to at least one of the opposite ends (24, 26) of spacer (10). Each end cap (10) includes an inner end (52) facing spacer (14), an outer end (50), and a side wall (54) extending between inner and outer ends (52, 50). Side wall (54) of each end cap (10) is formed for engagement with side wall (30) of spacer (12) to provide a mechanical connection between end cap (10) and spacer (12).</p>		

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SPACER ASSEMBLY FOR USE IN SPINAL SURGERIESBackground and Summary of the Invention

The present application relates to spinal instrumentation systems, more particularly to spacer assemblies for use in interbody fusion procedures of the spine. 5 Most particularly, the present invention relates to end cap caps for use with spacers that are used in spinal surgeries.

There has been a gradual acceptance of interbody fusion as a procedure for a number of spinal disorders. Interbody fusion procedures employ the use of 10 surgical mesh tubes, see for example "Chapter 10: Titanium Surgical Mesh for Vertebral Defect Replacement and Intervertebral Spacers", Gary L. Lowery and Jürgen Harms, *Manual of Internal Fixation of the Spine*, edited by John S. Thalgott and Max Aebi, Lippincoll-Raven Publishers, Philadelphia, 1996, which is incorporated herein by reference. The surgical mesh tubes are used to reinforce weak, bony tissues 15 in orthopaedic procedures and they act as a structural support for the spine. Moreover, a mesh pattern in the conventional surgical mesh tubes provides access for bone to grow and fuse within the tube. These surgical mesh tubes are often formed of titanium and are available in varying shapes and sizes. In addition, surgical mesh tubes can be trimmed on site by the surgeon to better provide an individual fit for each 20 patient.

Internal rings, connector screws, and fenestrated end plates have been added to the surgical mesh tube. See, for example, "Titanium Surgical Mesh for Vertebral Defect Replacement and Intervertebral Spacers", Gary L. Lowery and Jürgen Harms, *Manual of Internal Fixation of the Spine*, edited by John S. Thalgott 25 and Max Aebi, Lippincoll-Raven Publishers, Philadelphia, 1996. As discussed in the before mentioned article, conventional rings attach to the contoured mesh through the use of screws. The conventional rings strengthen the surgical mesh tube by acting as a reinforcement to aide in better distributing the axial loads previously taken wholly by the edge of the surgical mesh tube.

According to the present invention a spacer assembly is provided for 30 use in spinal surgeries. The spacer assembly comprises a spacer having opposite ends and a side wall extending between the opposite ends and at least one end cap coupled

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to at least one of the opposite ends of the spacer. Each end cap includes an inner end facing the spacer, an outer end, and a side wall extending between the inner and outer ends. The side wall of the end cap is formed for engagement with the side wall of the spacer to couple the end cap and spacer together.

5           In preferred embodiments, the spacer includes a passageway between the opposite ends and the inner end of the end cap extends into the passageway. The side wall of the end cap converges from the outer end toward the inner end to wedge fit the end cap in the spacer. In addition, the end cap includes at least one projection coupled to the side wall and formed to engage the spacer. The projection blocks  
10          sliding movement of the end cap in the passageway of the spacer. Also, the outer end includes an outer surface that promotes bone ingrowth, such as for example a porous coating or a serrated surface. Preferably, the engagement of the end cap side wall and the projection with the side wall of the spacer 12 provides the sole mechanical connection between the end cap and the spacer.

15          Alternatively, the side wall of the end cap is formed to include a slot extending between the outer and inner ends. The slot allows the side wall of the end cap to be compressed as it is inserted into the passageway of the spacer. Once positioned in the passageway, the side wall expands toward the side wall of the spacer to friction lock the end cap in the passageway of the spacer. At least one projection  
20          extends from the side wall of the compressible end cap for engagement with the spacer to block sliding movement of the end cap in the passageway.

Still further, the side wall of the spacer includes an outer surface and an alternative end cap is formed to extend over the opposite end of spacer and be coupled to the outer surface. The end cap includes an outer end, an inner end, and a side wall  
25          that extends between the outer and inner ends. In addition, the side wall includes a slot extending between the outer and inner ends. The slot allows the side wall of the end cap to be expanded as it is placed about the end of the spacer. Once positioned about the outer surface of the spacer, the side wall of the end cap contracts toward the side wall of the spacer to friction lock the end cap on the side wall of the spacer. At least  
30          one projection extends from the side wall of the compressible end cap for engagement with the spacer to block sliding movement of the end cap in the passageway.

Additional features of the invention will become apparent to those skilled in the art upon consideration of the following detailed description of preferred embodiments exemplifying the best mode of carrying out the invention as presently perceived.

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#### Brief Description of the Drawings

Fig. 1 is a perspective view of an anterior portion of a spine, a spacer assembly in accordance with the present invention, and showing a portion of one disc removed from the spine to form a disc space and the inter-vertebral spacer sized for  
10 extension into the disc space;

Fig. 2 is an exploded isometric view of the spacer assembly of Fig. 1 showing the spacer assembly including a spacer and two end caps of the present invention;

Fig. 3 is a side view of the end cap of Fig. 2 showing the end cap  
15 including an outer end, an inner surface, a tapered side wall extending between the outer and inner surfaces, teeth extending outwardly from the side wall, and the outer end including a serrated surface;

Fig. 4 is a bottom view of the end cap of Fig. 3 showing the side wall including an outer surface and an inner surface defining a passageway and the teeth  
20 extending from the outer surface in a spaced-apart relationship relative to one another;

Fig. 5 is a top view of the end cap of Fig. 3 showing the serrated surface of the outer end;

Fig. 6 is an isometric view of the spacer assembly of Fig. 2 following insertion of the end caps into the spacer showing the end caps having a serrated outer  
25 side and teeth spaced apart about the periphery of the end cap and engaging the spacer to hold the end cap in place;

Fig. 7 is a cross-sectional view taken along the lines 7-7 of Fig. 6 showing the spacer including a cylindrical side wall defining a passageway and two end caps extending into the passageway and engaging the cylindrical side wall to wedge the  
30 end caps and spacer together;

Fig. 8 is a bottom view of an end cap in accordance with an alternative embodiment of the present invention showing the end cap having an oval shape;

Fig. 9 is a side view of the end cap of Fig. 8 showing the end cap having an outer end with a serrated surface, and inner end, and a tapered side wall converging from the outer end toward the inner end;

Fig. 10. is a top view of the end cap of Fig. 8 showing the serrated  
5 surface;

Fig. 11 is an isometric view of the spacer of Fig. 2 and end caps in accordance with an alternative embodiment of the present invention showing the end caps having a porous coated top surface and a lip extending about the circumference of the end cap to prevent the end cap from slipping down within a passageway of the  
10 surgical mesh tube;

Fig. 12 is a cross-sectional view taken along the lines 12-12 of Fig. 11 showing the tapered side wall of the end cap and the lip engaging peaks of the side wall to prevent the end caps from sliding in the passageway of the spacer;

Fig. 13 is a top view of an end cap in accordance with an alternative  
15 embodiment of the present invention showing the end cap to include a solid plate formed with apertures therein;

Fig. 14 is a side view of the end cap of Fig. 13 showing the apertures, in phantom, extending between the outer and inner ends of the end plate;

Fig. 15 is a top view of an end cap in accordance with an alternative  
20 embodiment of the present invention showing the end cap including a side wall having a slot formed therein and teeth coupled to the side wall;

Fig. 16 is a perspective view of the end cap of Fig. 15 showing the slot extending between the outer and inner ends of the end cap to permit compression of the end cap;

Fig. 17 is a side view of the end cap of Fig. 15 showing the side wall including a first side wall portion and a tapered second side wall portion;  
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Fig. 18 is a perspective view of an end cap in accordance with an alternative embodiment of the present invention showing the end cap outer and inner ends, a side wall extending between the outer and inner ends, and teeth extending  
30 upwardly from the outer end and away from the side wall;

Fig. 19 is a perspective view of an end cap in accordance with an alternative embodiment of the present invention showing the end cap including a side

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wall having an outer surface and an irregularly shaped inner surface defining a passageway;

Fig. 20 is a top view of the end cap of Fig. 19 showing the inner surface of the side wall defining pockets that are spaced-apart from one another;

5 Fig. 21 is a front view of the end cap of Fig. 20 showing the slot extending between the outer and inner ends;

Fig. 22 is a side view of the end cap of Fig. 20 showing the side wall including a first side wall portion and a tapered second side wall portion;

10 Fig. 23 is a perspective view of an end cap in accordance with an alternative embodiment of the present invention showing the end cap including a side wall formed without a chamfer;

Fig. 24 is a top view of the end cap of Fig. 23 showing the outer end including apertures formed therein for receiving a compression instrument;

15 Fig. 25 is a back view of the end cap of Fig. 23 showing the outer and inner end positioned to lie at an angle relative to one another;

Fig. 26 is a side view of the end cap of Fig. 23 showing the outer and inner end positioned to lie at an angle relative to one another;

20 Fig. 27 is a top view of an end cap in accordance with an alternative embodiment of the present invention showing the end cap including a crescent-shaped side wall formed for expansion from its original shape to fit over the end of the spacer;

Fig. 28 is a top perspective view of the end cap of Fig. 27 showing the side wall including an inner surface defining a passageway and a lip extending from the side wall into the passageway;

25 Fig. 29 is a bottom view of the end cap of Fig. 27 showing the lip extending into the passageway; and

Fig. 30 is a bottom perspective view of the end cap of Fig. 27.

#### Detailed Description of the Drawings

End caps 10 are provided in accordance with the present invention for 30 use with vertebral body spacers 12 in a spine 14 during disc-replacement or vertebral body replacement surgery to form a spacer assembly 100. As shown in Fig. 1, end cap 10 is coupled to spacer 12 and is suitable for placement into an anterior portion 18 of

spine 14. This placement may be done to replace an inter-vertebral disc 20 or to replace a vertebral body 22 or multiple versions of each.

Spacer 12 is, for example, a surgical mesh tube constructed of titanium mesh. Spacer 12 houses bone (not shown) such that spacer 12 fuses to spine 14 to where there will be generally no movement between spacer 12 and spine 14 to reduce a patient's pain. Spacer 10 includes opposite ends 24, 26 and a cylindrical side wall 30 extending between ends 24, 26 and defining a passageway 32 having a predetermined inner diameter 28. Opposite ends 24, 26 each include peaks 34 and valleys 36 that form detents 38. In addition, side wall 30 has an inner surface 40, an outer surface 42, and apertures 44 extending between inner and outer surfaces 40, 42. As shown in Fig. 2, apertures 44 are generally diamond shaped and positioned to lie in a diamond-like pattern relative to one another. It is appreciated, however, that apertures 44 may have a variety of shapes and sizes and be positioned in a variety of patterns to promote bone ingrowth during the healing process. In addition to titanium mesh, end caps 10 are suitable for use with other forms of spacers that are also used in anterior portion 18 of spine 14. Specifically, end caps 10 are suitable for use with mesh spacers constructed in a variety of sizes and from a variety of metals, composites, tissue, or bone, or any other type of mesh spacer designed to be placed into spine 14 as a spinal spacer.

Referring now to Fig. 1, spine 14 includes anterior portion 18 and a posterior portion 46. In addition, spine 14 is constructed of vertebral bodies 48, seven of which are cervical vertebral bodies, twelve of which are thoracic vertebral bodies, and five of which are lumbar vertebral bodies. End caps 10 of the present invention are coupled to spacer 12 that is delivered to anterior portion 18 or posterior portion 46 of spine 14 whether it is cervical, thoracic or lumbar. Spacers 12 can be designed to replace either disc 20, as shown in Fig. 1, or vertebral body 48.

As shown in Fig. 2, end cap 10 is coupled to either end 24, 26 of spacer 12 for use in interbody fusion surgeries. End cap 10, remains at either end 24, 26 of spacer 12 without slipping down within passageway 32. As shown in Figs. 2-5, end cap 10 is formed to include an outer end 50, an inner end 52, and a tapered side wall 54 converging from outer end 50 toward inner end 52. Referring now to Fig. 4, side wall 54 includes a generally cylindrical inner surface 56 having a constant diameter 58 and defining a passageway 60 and an outer surface 62. While end cap 10 is shown in

Figs. 4 and 5 with generally circular outer and inner ends 50, 52, it is appreciated that outer and inner ends 50, 52 may be formed in a variety of shapes to cooperate with a variety of opposite ends 24, 26 of spacers 12 and may be positioned to lie generally parallel to one another or angled relative to one another. It is also appreciated that end 5 caps 10 may vary in size to cooperate with a variety of spacers 12.

Outer surface 62 of side wall 54 cooperates with inner surface 40 of side wall 30 to form a friction lock between end cap 10 and spacer 12, eliminating the necessity of additional parts to couple end cap 10 and spacer 12 together. Referring now to Fig. 4, outer surface 62 has first outer diameter adjacent 64 to outer end 50 and a second outer diameter 66 adjacent to inner end 52. First outer diameter 64 is greater than second outer diameter 66 so that outer surface 62 of side wall 54 converges at about an 8 degree taper, as shown in Fig 3. It is appreciated that side wall 54 may be formed at various angles so long as a friction lock is formed between end cap 10 and spacer 12 in accordance with the present disclosure. In addition, first 10 outer diameter 64 of side wall 54 adjacent to outer end 50 of end cap 10 is generally equivalent to diameter 28 of spacer 14 so that outer end 50 is positioned to lie adjacent to end 24 of spacer 12.

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As shown in Fig. 3, outer surface 62 is further formed to include projections or interdigitating teeth 78 that are spaced apart from another adjacent to outer end 50 of end cap 10. Referring now to Figs. 6 and 7, teeth 78 are positioned on outer surface 62 such that when end cap 10 has been wedged within spacer 12, teeth 78 rest against valleys 36 of opposite ends 24, 26. Because each tooth 78 rests within detent 38, end cap 10 is thus prohibited from slipping within passageway 32 of spacer 12. The engagement of side wall 54 and teeth 78 with side wall 30 of spacer 12 20 provides the sole mechanical connection between end cap 10 and spacer 12. While end cap 10 is shown with seven teeth 78, it is appreciated that greater or fewer than seven teeth 78 may be coupled to outer surface 62 in accordance with the present disclosure.

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Referring now to Fig. 6, outer end 50 of end cap 10 includes an outer side 68 formed to promote bone ingrowth. One type of outer side 68 that promotes bone ingrowth is for example, a porous coated finish 69, as shown in Figs. 11 and 12. An alternative outer side 68 suitable for bone growth is a serrated outer surface 70. See Figs. 1-7. Serrated surface 70 of end cap 10 includes peaks 74 and valleys 76.

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Peaks 74 and valleys 76 provide a rough surface and reduce movement against vertebral body 48. Although porous and serrated outer finishes 70 are described, it is appreciated that a variety of anti-skid surfaces that promote bone ingrowth may be used in accordance with the present disclosure.

5 When replacing disc 20 or vertebral bodies 48, the surgeon first removes damaged disc 20 or bodies 48 to create a space 80. See for example disc space 80 in Fig. 1. Once space 80 is formed, the surgeon selects the appropriate size of spacer 12 and at least one corresponding end cap 10. While only one end cap 10 and end 24 of spacer 12 will be discussed hereafter it is appreciated that the description 10 and claims applies to greater than one end cap 10 and end 26. Referring now to Fig. 2, inner end 52 of end cap 10 is aligned with end 24 of spacer 12. Inner end 52 is inserted into passageway 32, as shown in Fig. 7, until outer surface 62 is wedged into engagement with side wall 30 of spacer to form a spacer assembly 100. At that time, teeth 78 will be positioned to lie within detents 38 preventing further migration of end 15 cap 10 into passageway 32 of spacer 12. Once end cap 10 is coupled to spacer 12, spacer assembly 100 may be inserted into space 80 using a variety of surgical techniques.

In an alternative embodiment of the present invention it is provided that an end cap 110 has an oval shape. See, Figs. 8-10. End cap 110 is formed to 20 cooperate with an oval-shaped spacer (not shown) that is formed identically to spacer 12, except for the oval shape of side wall 30. End cap 110 is formed similarly to end cap 10 and like reference numerals are used to denote like components. As shown in Fig. 8, end cap 110 has a first ring width 164 adjacent to outer end 50 and a second ring width 166 adjacent to inner end 152. First ring width 164 is greater than second 25 ring width 166, so that outer surface 62 of side wall 54 converges from outer end 50 toward inner end 152 and forms about an 8 degree taper, as shown in Fig. 9. It is appreciated that the angle of taper may vary so long as end cap 110 may be wedged in spacer 12. Additionally, end cap includes ten teeth 78 coupled to outer surface 62. It is appreciated, however, that greater or fewer than ten teeth 78 may be coupled to 30 outer surface 62.

In an alternative embodiment of the present invention, an end cap 210 is provided. End cap 210 is formed similarly to end cap 10 and like reference numerals

are used to denote like components. As shown in Figs. 11 and 12, end cap 210 includes a single projection or outer lip 282 extending from side wall 54 adjacent to outer end 50. Outer lip 282 extends about the circumference of outer end 50 and includes an inner face 284 that rests on peaks 34 of opposite ends 24, 26 respectively  
5 to prevent end cap 210 from slipping within passageway 32 of spacer 12. The engagement of side wall 54 and teeth lip 282 with side wall 30 of spacer 12 provides the sole mechanical connection between end cap 210 and spacer 12.

In still another embodiment of the present invention an end cap 310 is provided. As shown in Figs 13 and 14, end cap 310 is a solid plate 358 shown to have  
10 an oval shape and is suited particularly for use with osteoporotic bone. End cap 310 includes an outer end 350, an inner end 352, and a tapered side wall 354 converging from outer end 350 toward inner end 352. Referring now to Fig. 14, side wall 354 includes an outer surface 362. Outer surface 362 of side wall 354 is tapered similarly to outer surface 62 to form a friction lock with spacer 12. The engagement of side  
15 wall 354 with side wall 30 of spacer 12 provides the sole mechanical connection between end cap 310 and spacer 12. In addition, apertures 360 extend between outer and inner ends 350, 352. While end cap 10 is shown in Figs. 13 and 14 with generally oval outer end 350, it is appreciated that end cap 310 may be shaped similarly to end cap 10 or in a variety of shapes to cooperate with a variety of spacers 12 and/or be  
20 formed without apertures 360. It is also appreciated that end caps 10 may vary in size to cooperate with a variety of spacers 12. Further, it is appreciated that end cap 310 could be formed to include, outer teeth 54, and/or an outer lip 56.

Another embodiment of the present invention is shown in Figs. 15-17. End cap 410 includes an outer end 414, an inner end 416, and first and second side walls 420, 429 extending between outer and inner ends 414, 416. Second side wall 429 is a chamfer formed to facilitate inserting end cap 410 into spacer 12 and is tapered similarly to side wall 54 from first side wall portion 420 toward inner end 416. Second side wall 429 is shown in Fig. 15. First and second side walls 420, 429 share inside surface 418 defining passageway 422. First side wall portion 420 also includes  
25 outside surface 421 while second side wall 429 includes outside surface 423. Six teeth 454 extend around the periphery of first side wall portion 420 and are coupled outside surface 421 in the same manner as teeth 78. Teeth 454 prevent end cap 410 from  
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recessing too far within spacer 12. The engagement of first side wall portion 420 and teeth 454 with side wall 30 of spacer 12 provides the sole mechanical connection between end cap 410 and spacer 12. It is appreciated that the number of teeth 454 may be greater or fewer than six in accordance with the present disclosure. It is also  
5 appreciated that outer and inner ends 414, 416 may be positioned to lie generally parallel to one another or may be angled relative to one another.

As shown in Figs. 15 and 16, end cap 410 also includes inside cross-sectional ends 424, 426 so that end cap 410 has a split-ring shape. Cross-sectional ends 424, 426 define a slot or cut-out portion 428. Slot 428 allows end cap 410 to be  
10 compressed in direction 430 as it is inserted into passageway 32 of spacer 12. End cap 410 is shown in its fully opened position in Figs. 15 and 16 so that a lower outer diameter 432 (see Fig. 17) is greater than diameter 28 of passageway 32. As end cap 410 is compressed together in direction 430, it is sized for insertion within passageway 32 of spacer 12. Once inserted in spacer 12, end cap 410 expands toward its original  
15 shape and size thereby pressing against inner surface 40 of spacer 12 to insure a secure and tight fit.

Fig. 18 shows another alternate embodiment of the present invention. End cap 510 is identical to end cap 410 in nearly all respects and like reference numerals will be used to denote like components. End cap 510 includes teeth 554  
20 coupled to outer surface 414 and extending away from side wall 420. Thus, outer end 414 is textured to provide further fixation for bone ingrowth.

As shown in Figs. 19-22, end cap 610 is provided. End cap 610 is formed similarly to end cap 410 and like reference numerals will be used to denote like components. End cap 610 is formed to include a passageway 622 extending between  
25 outer and inner ends 414, 416. Passageway 622 is irregular in shape to maximize a surface area of an inner surface 632 of first and second side walls 420, 429. As shown in Figs. 19 and 20, inner surface 632 defines pockets 634 spaced apart from one another. While end cap 610 having irregularly shaped passageway 622 with curved pockets 634 is illustrated and described, it is appreciated that end cap 610 may be  
30 formed to include a passageway having any number of shapes and sizes in accordance with the present disclosure.

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Referring now to Figs. 23-26, end cap 710 is provided in accordance with the present invention. End cap 710 is formed similarly to end cap 410 and like reference numerals will be used to denote like components. End cap 710 includes a side wall 720 extending between inner and outer ends 714, 716. Side wall 720 is 5 formed without a chamfer. In addition, as shown in Figs. 25 and 26, inner and outer ends 714, 716 are positioned to lie at a predetermined angle 731 relative to one another and are formed to include different surfaces 730, 732, such as, for example porous surface 69 and serrated surface 70. As shown in Figs. 23 and 24, end cap 710 includes apertures 734 that receive an instrument (not shown) used to compress end cap in 10 direction 430 to be inserted into passageway 32 of spacer 12. Since side wall 720 is not tapered, the surgeon may insert either inner or outer end 714, 716 into passageway 32 so that the desired surface 69, 70 faces away from passageway 32 for engagement with vertebral body 48. It is appreciated that inner and outer ends may be positioned at a variety of angles relative to one another and may be positioned to lie in a generally 15 parallel relationship as well in accordance with the present disclosure.

Figs. 27-30 illustrate an end cap 810 in accordance with still another embodiment of the present invention. End cap 810 fits on outer surface 42 of spacer 12 instead of within passageway 32 as previously described end caps 10, 110, 210, 310, 410, 510, 610, and 710. End cap 810 includes an outer end 814, an inner end 20 816, and a crescent-shaped side wall 820 extending between outer and inner ends 814, 816. It is appreciated that end cap may be formed into circular, oval, or any complex polynomial shape in accordance with the present disclosure.

Crescent-shaped side wall 820 includes an inside surface 818 defining a passageway 822 and outside surface 821. A projection or lip 854 extends about the 25 periphery of side wall 820 adjacent to outer end 814 into passageway 822. Lip 854 prevents end cap 810 from recessing too far within spacer 12. It is appreciated that the number of lips 854 may be greater than one in accordance with the present disclosure. It is also appreciated that outer and inner ends 814, 816 may be positioned to lie generally parallel to one another or may be angled relative to one another.

As shown in Figs. 27 and 28, end cap 810 also includes inside cross-sectional ends 824, 826 defining a slot or cut-out portion 828. Slot 828 allows end 30 cap 810 to expand in direction 830 such that inner surface 818 is sized to extend about

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outer surface 42 of side wall 30 of spacer 12. Once positioned about end 24 of spacer 12, end cap 810 compresses toward its original shape and size shown in Fig. 27, thereby pressing against outer surface 42 of spacer 12 to insure a secure and tight fit. Lip 854 contacts end 24 of spacer 12 to resist axial loads. In addition, lip provides the 5 same support as teeth 78 provide such that end cap 810 cannot recess about side wall 30 of spacer 12 toward end 26. The engagement of side wall 820 and lip 854 with side wall 30 of spacer 12 provides the sole mechanical connection between end cap 810 and spacer 12.

Therefore, end caps 10, 11, 210, 310, 410, 510, 610, 710, and 810 are 10 formed to cooperate with spacers to form spacer assemblies for use in spinal surgeries. End caps 10, 11, 210, 310, 410, 510, 610, 710, and 810 reinforce spacers that are used in spinal and trauma surgeries to increase stability and resistance to shear forces. End caps of the present invention fit within the spacer, on the outside of the spacer, or over 15 the spacer and are coupled to the spacer by a taper or by split-ring forces. End caps 10, 11, 210, 310, 410, 510, 610, 710, and 810 are preferably self-locking in or on spacer 12. In addition, end caps of the present invention may be formed with a variety of different polynomial shapes to fit a variety of spacer shapes and have a variety of 20 surface coatings or textures to promote bone growth or anti-skid features to prevent movement against bone increasing stability. At least one projection extends from the end cap toward the spacer to prohibit the end cap from slipping within a passageway of the spacer body.

Although the invention has been described in detail with reference to a preferred embodiment, variations and modifications exist within the scope and spirit of the invention as described and defined in the following claims.

CLAIMS:

1. A spacer assembly for use in spinal surgeries, the assembly comprising:
  - 5 a spacer formed to include opposite ends and a side wall extending between the opposite ends, and at least one end cap coupled to at least one of the opposite ends, each of the at least one end caps including an inner end facing the spacer, an outer end, and a side wall extending between the inner and outer ends and engaging the side wall of the spacer to provide a mechanical connection between the at least one cap and the spacer.
  - 10 2. The spacer assembly of claim 1, wherein the spacer includes a passageway extending between the opposite ends and the inner end of the end cap extends into the passageway.
  - 15 3. The spacer assembly of claim 2, wherein the side wall of the end cap converges from the outer end toward the inner end.
  4. The spacer assembly of claim 3, wherein the end cap includes a projection coupled to the side wall of the end cap and formed for engagement with the spacer.
  - 20 5. The spacer assembly of claim 3, wherein the outer end is formed to include a porous coating.
  6. The spacer assembly of claim 3, wherein the outer end includes a serrated surface.
  - 25 7. The spacer assembly of claim 2, wherein the end cap includes a projection that extends away from the side wall of the end cap into engagement with the spacer.
  8. The spacer assembly of claim 2, wherein the end cap includes projections spaced-apart from one another and formed for engagement with the spacer.
  9. The spacer assembly of claim 2, wherein the side wall of the end 30 cap includes a slot extending between the outer and inner ends.
  10. The spacer assembly of claim 9, wherein the end cap includes projections spaced-apart from one another and formed for engagement with the spacer.

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11. The spacer assembly of claim 1, wherein the side wall of the spacer includes an outer surface and the side wall of the end cap is coupled to the outer surface.

12. The spacer assembly of claim 11, wherein the side wall of the 5 end cap includes a slot extending between the outer and inner ends.

13. The spacer assembly of claim 12, wherein the side wall of the end cap defines a passageway and the end cap further includes at least one projection extending into the passageway of the side wall and engaging the spacer.

14. The spacer assembly of claim 1, wherein the side wall of the end 10 cap includes an inner surface that defines a passageway between the inner and outer ends.

15. The spacer assembly of claim 14, wherein the inner surface of the side wall is generally cylindrical in shape.

16. The spacer assembly of claim 1, wherein the end cap is formed 15 as a solid plate including apertures extending between the outer and inner surfaces.

17. The spacer assembly of claim 1, wherein at least one of the ends of the spacer includes peaks and valleys.

18. The spacer assembly of claim 17, wherein the end cap includes projections coupled to the side wall of the end cap and formed for extension between 20 the peaks and engagement with the valleys of the spacer.

19. The spacer assembly of claim 17, wherein the end cap includes a projection coupled to the side wall of the end cap and formed for engagement with the peaks of the spacer.

20. A spacer assembly for use in spinal surgeries, the assembly 25 comprising:

a spacer formed to include opposite ends and a side wall extending between the opposite ends, and

end caps coupled to the opposite ends respectively, each end caps including an inner end facing the spacer, an outer end, a side wall extending between 30 the inner and outer ends, and at least one projection extending from the side wall, the engagement of the end cap side wall with the side wall of the spacer and the at least

one projection with the side wall with the respective opposite end of the spacer providing the sole mechanical connection between the spacer and the end caps.

21. The spacer assembly of claim 20, wherein the opposite ends are formed to include peaks and valleys.

5 22. The spacer assembly of claim 21, wherein the at least one projection engages at least one of the peaks of the respective opposite ends.

23. The spacer assembly of claim 21, wherein the at least one projection engages at least one of the valleys of the respective opposite ends.

10 24. The spacer assembly of claim 20, wherein the spacer includes a passageway extending between the opposite ends and the inner end of the end cap extends into the passageway.

25. The spacer assembly of claim 24, wherein the side wall of the end cap includes a slot extending between the outer and inner ends.

15 26. The spacer assembly of claim 24, wherein the side wall of the end cap is tapered.

27. The spacer assembly of claim 20, wherein the side wall of the spacer includes an outer surface and the side wall of the end cap is coupled to the outer surface.

20 28. The spacer assembly of claim 27, wherein the side wall of the end cap includes a slot extending between the outer and inner ends.

29. The end cap of claim 20, wherein the outer end of the end cap is generally circular in shape.

30. The end cap of claim 20, wherein the outer end of the end cap includes a coating formed to promote bone growth.

25 31. The end cap of claim 25, wherein the side wall of the end cap includes a generally cylindrical inner surface defining a passageway.

32. An end cap formed for use with a spacer having opposite ends in a spinal surgery, the end cap comprising:

30 an inner end, an outer end, a side wall extending between the inner and outer ends, and at least one projection extending from the side wall, the side wall being adapted to provide a mechanical connection between the end cap and the spacer to couple the end cap and spacer together.

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33. The end cap of claim 32, wherein the side wall includes an inner surface defining a passageway and an outer surface.

34. The end cap of claim 33, wherein the inner surface of the side wall is generally cylindrical in shape.

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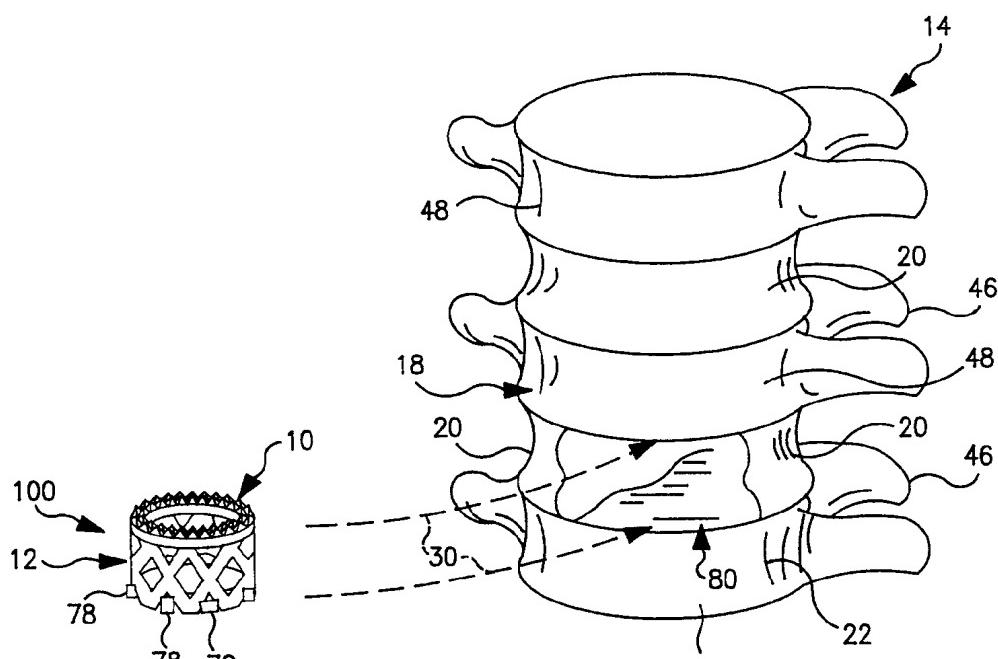


FIG. 1

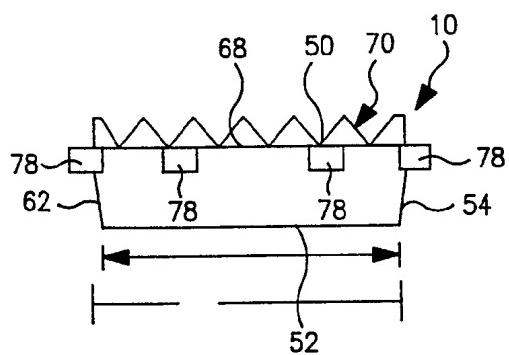


FIG. 3

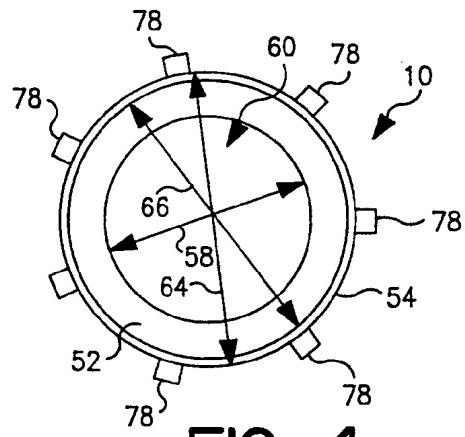


FIG. 4

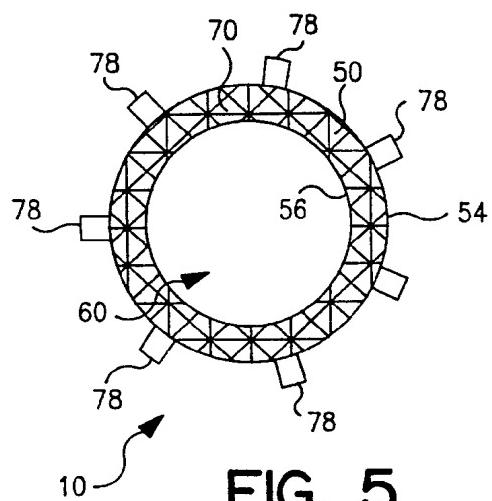


FIG. 5

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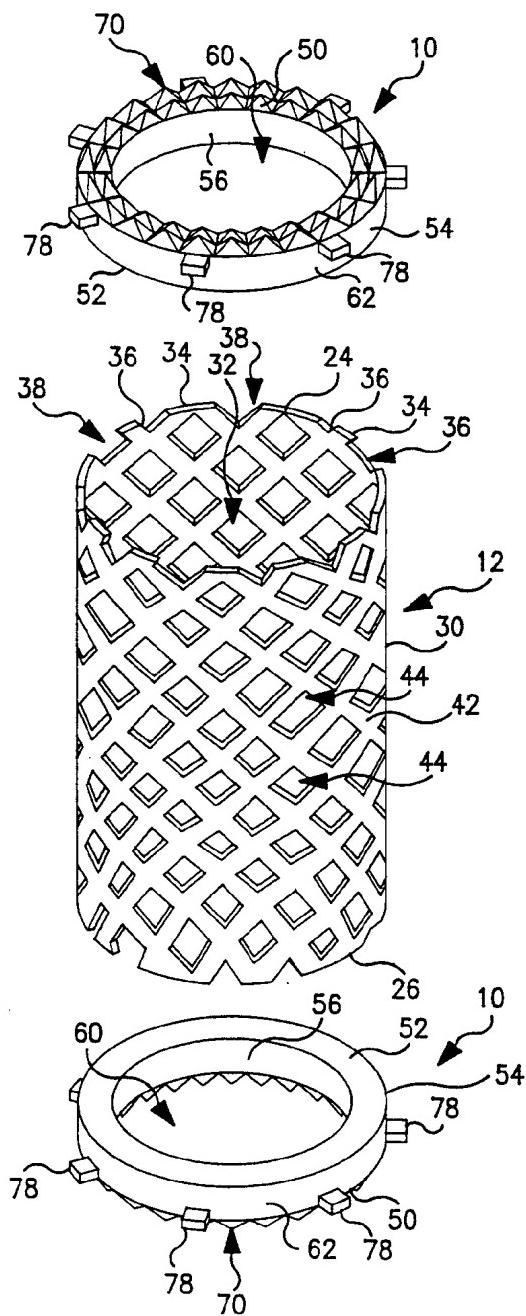


FIG. 2

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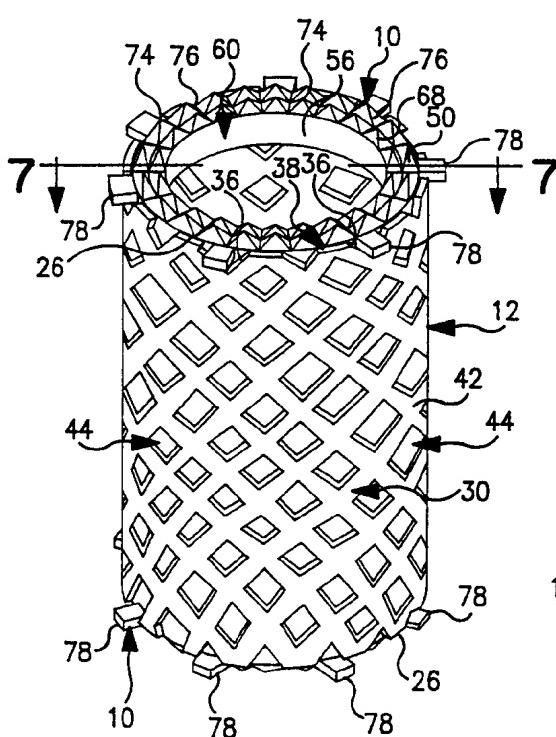


FIG. 6

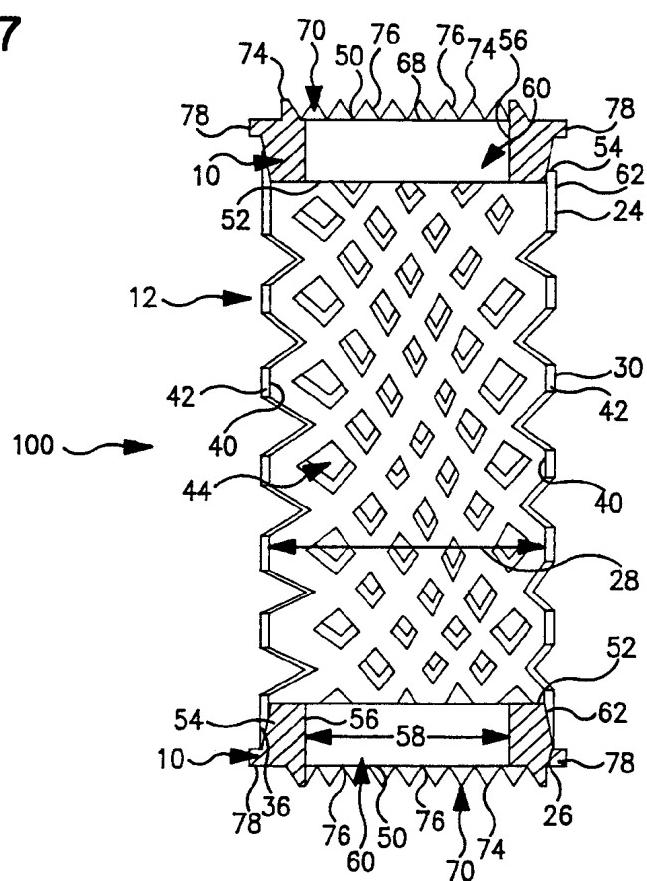


FIG. 7

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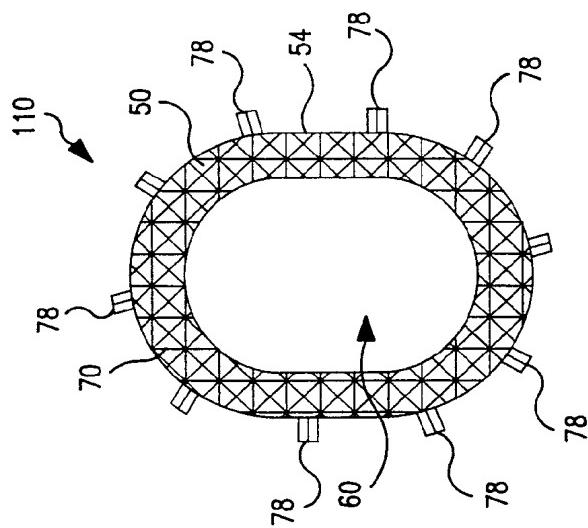


FIG. 10

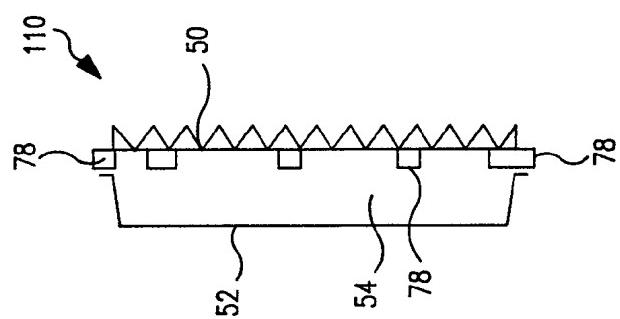


FIG. 9

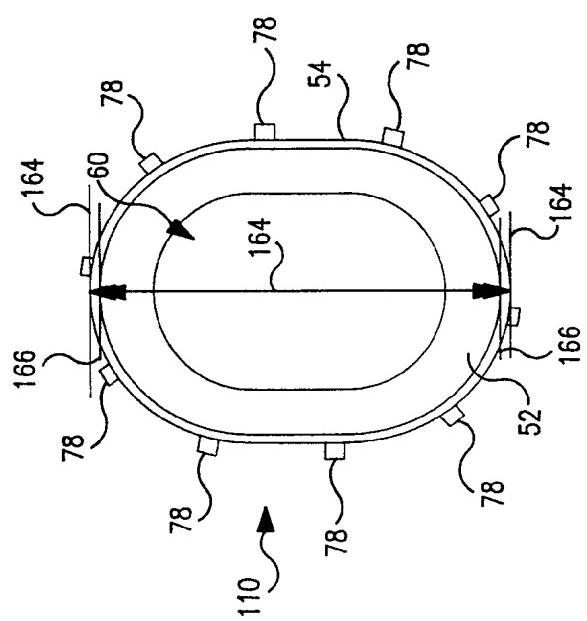
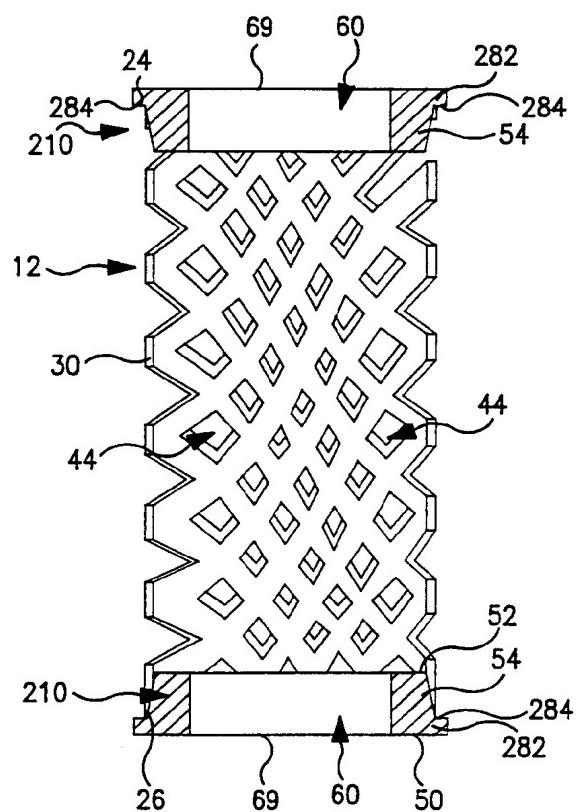
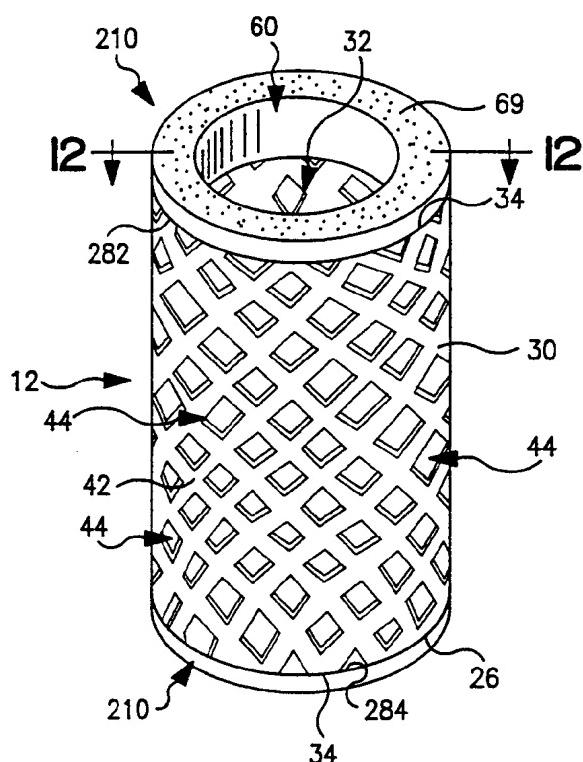


FIG. 8



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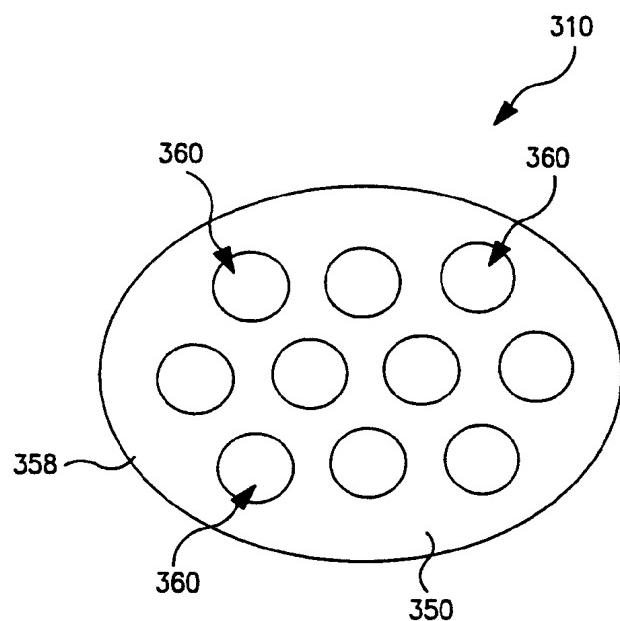


FIG. 13

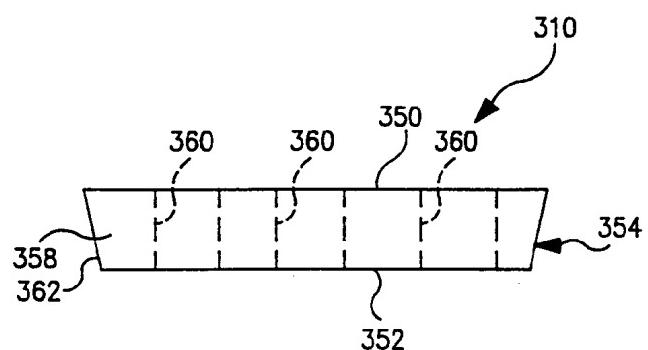
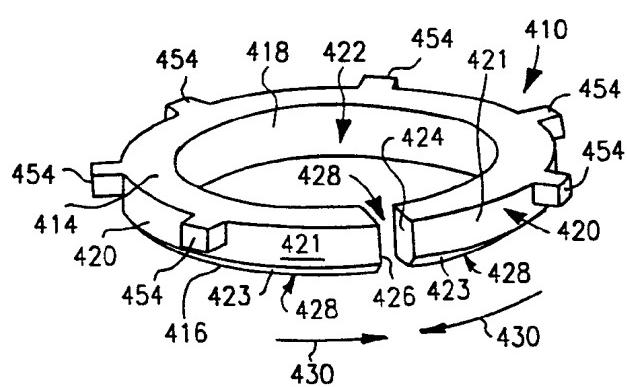
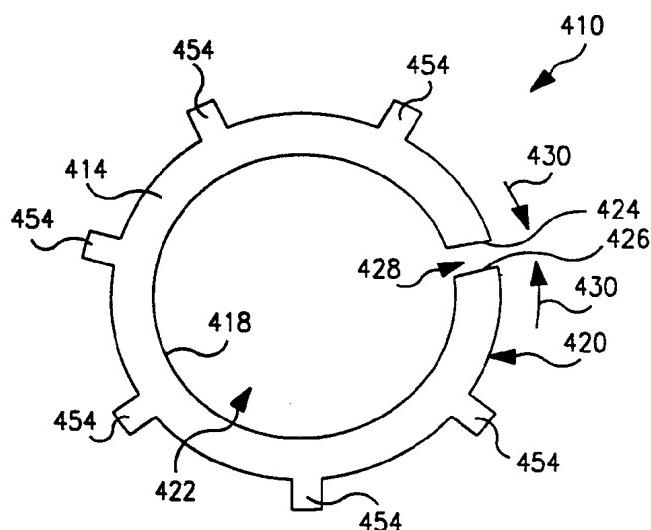
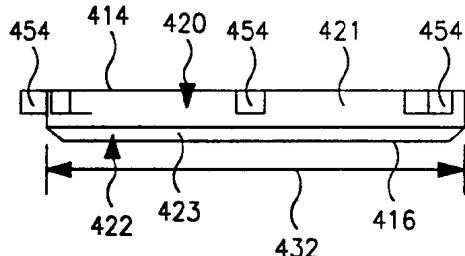
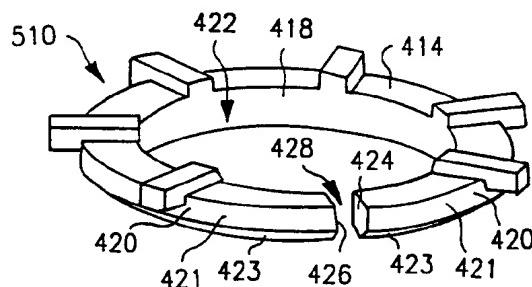


FIG. 14

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**FIG. 16****FIG. 15****FIG. 17****FIG. 18**

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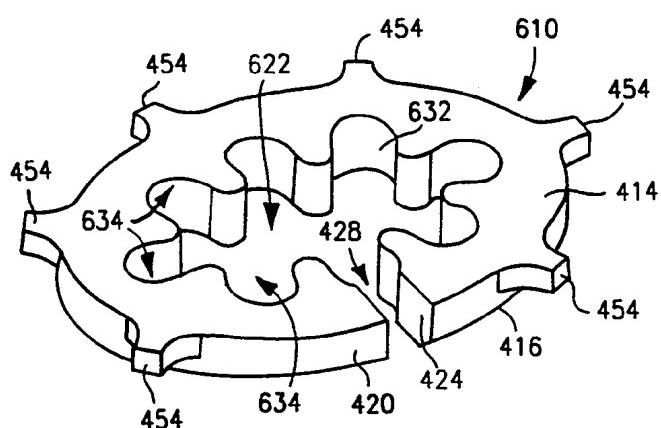


FIG. 19

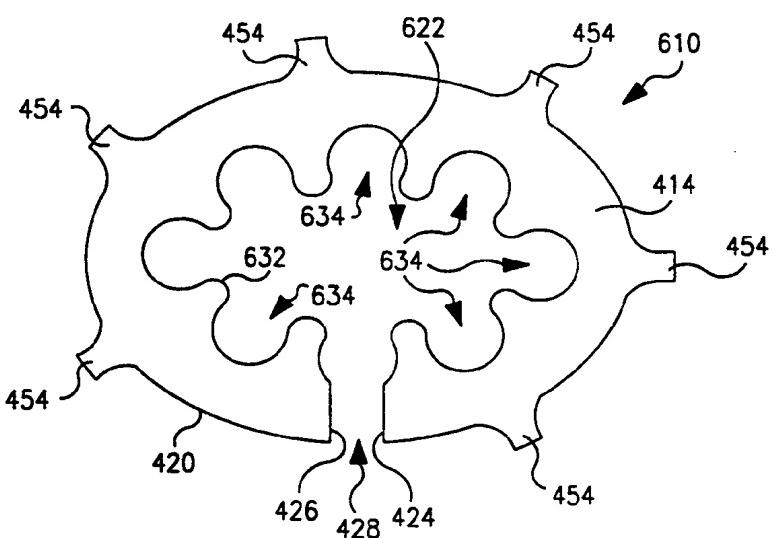


FIG. 20

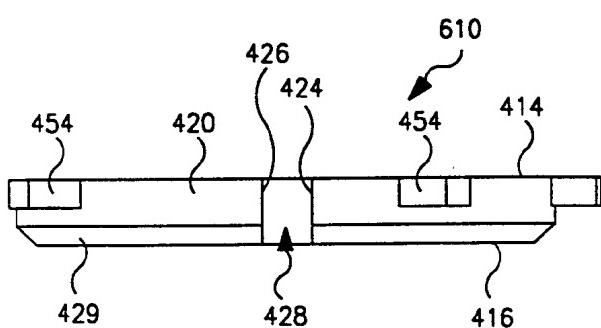


FIG. 21

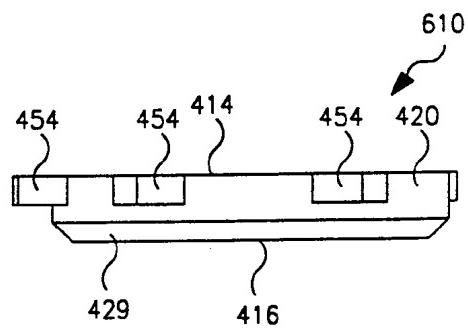


FIG. 22

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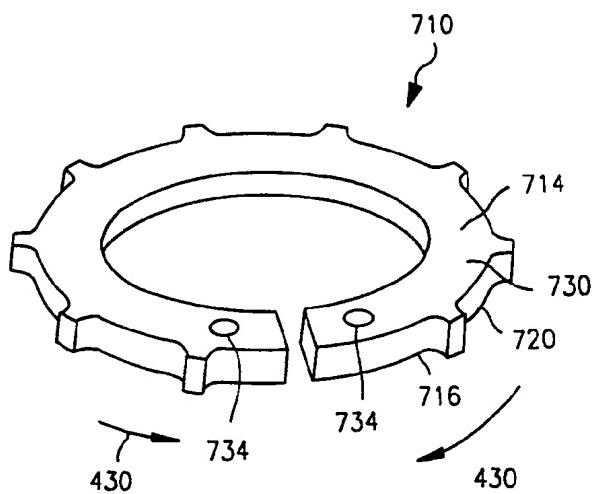


FIG. 23

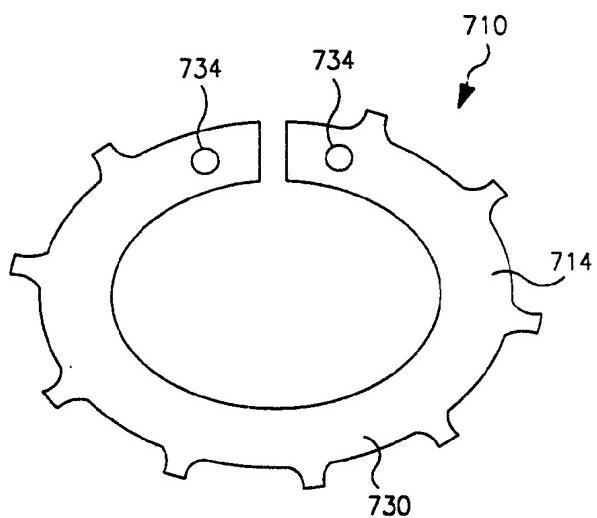


FIG. 24

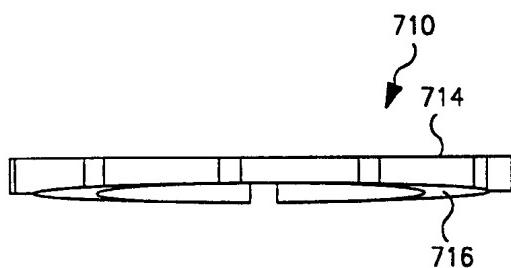


FIG. 25

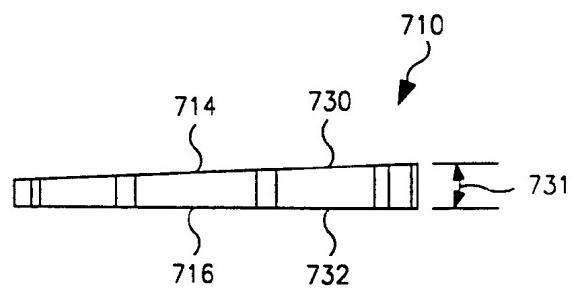


FIG. 26

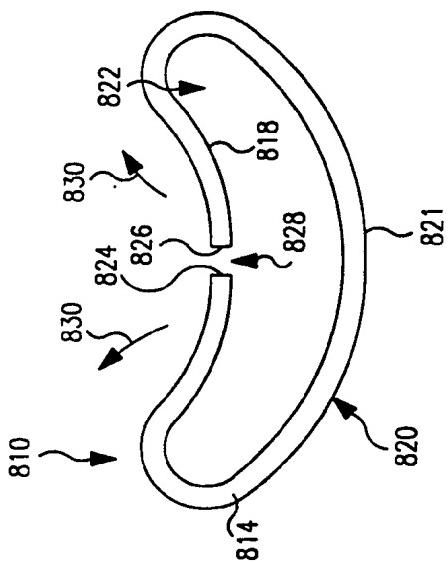


FIG. 27

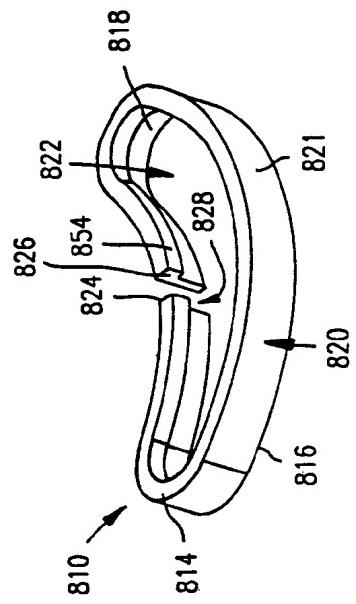


FIG. 28

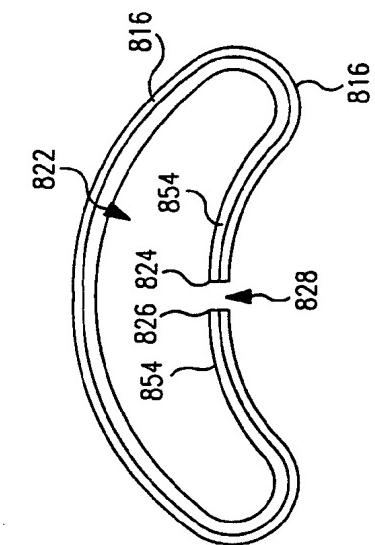


FIG. 29

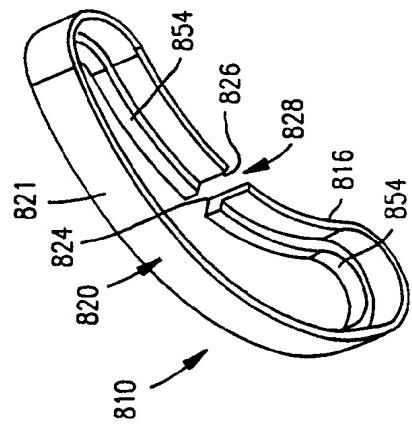


FIG. 30

# INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 98/27476

**A. CLASSIFICATION OF SUBJECT MATTER**

IPC 6 A61F2/44

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

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**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 727 196 A (HARMS) 21 August 1996	1,2,7,8, 11,14, 16-24, 27,32,33
Y	see the whole document	3,4,9, 10,12, 13,15, 25,26, 28-30,34
Y	EP 0 666 068 A (SULZER MEDIZINALTECHNIK) 9 August 1995 see column 5, line 3 - line 20; figure 2	3,4,26
Y	FR 2 733 413 A (JBS) 31 October 1996	9,10,12, 13,25,28
A	see abstract; figures 1,2	6
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## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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Y A	DE 40 12 622 C (ESKA MEDICAL LÜBECK MEDIZINTECHNIK) 18 July 1991 see column 4, line 63 - line 64; figures 1, 2 ---	30 5
X	EP 0 268 115 A (BIEDERMANN) 25 May 1988 see column 4, line 3 - line 17; figures 8, 9 ---	1
A	EP 0 732 093 A (SOFAMOR DANEK GROUP) 18 September 1996 see column 12, line 34 - line 41; figures 8, 9 ---	5, 30
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Information on patent family members

Inte... onal Application No

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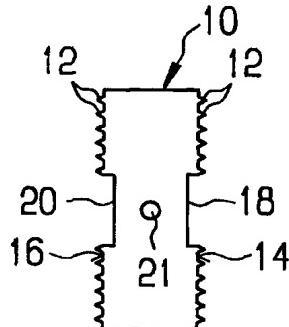
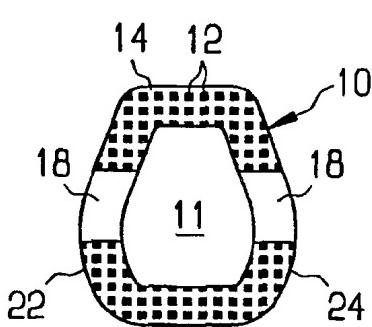
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(21) International Application Number:	PCT/EP99/00433		(81) Designated States:	CA, JP, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).
(22) International Filing Date:	22 January 1999 (22.01.99)			
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(71) Applicant (for CA only):	SYNTHES (U.S.A.) [US/US]; 1690 Russell Road, P.O. Box 1766, Paoli, PA 19301-1222 (US).			
(72) Inventors:	PAUL, David, C.; 1513 Valley Road, Drexel Hill, PA 19026 (US). EMCH, Hansjuerg, W.; 1527 Spruce Street, Philadelphia, PA 19102 (US). SCHENK, Beat; 59 Cobblestone Drive, Paoli, PA 19301 (US). CARVER, Jeffrey, L.; 1011 Welsh Ayres Way, Downingtown, PA 19335 (US). BAKER, Kelly, J.; 1878 Shadyside Road, Coatesville, PA 19320 (US).			
(74) Agent:	LUSUARDI, Werther; Dr. Lusuardi AG, Kreuzbühlstrasse 8, CH-8008 Zürich (CH).			

(54) Title: ALLOGENIC INTERVERTEBRAL IMPLANT



## (57) Abstract

An allogenic intervertebral implant (10) for fusing vertebrae is disclosed. The implant (10) is an annular plug conforming in size and shape with end plates of vertebrae. The implant has either an exterior surface identical to that of the harvest bone or an exterior surface machined to have a uniform shape such as an oval or a rectangle. The top and bottom surfaces (14, 16) of the implant (10) have a plurality of teeth (12) to resist expulsion and provide initial stability. The top and bottom surfaces (14, 16) can be either flat planar surfaces or curved surfaces. Preferably, the anterior height of the implant is greater than the posterior height so that the implant is wedge-shaped profile to help restore disc height and the natural curvature of the spine. In one embodiment, the top and bottom surfaces each have a channel oriented in the anterior, lateral, or antero-lateral direction for receiving a surgical instrument. The implant can also have a hole for attachment of an inserter. Although the interior space formed by the annular plug can be the natural shape defined by the medullary canal, the medullary canal walls can be machined so that the implant has a uniform interior space.

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## ALLOGENIC INTERVERTEBRAL IMPLANT

This invention concerns a device in accordance with the pre-characterising portion of Claim 1. More particularly, it refers to an allogenic intervertebral implant for use in the treatment of back pain.

A number of medical conditions such as compression of spinal cord nerve roots, degenerative disc disease, and trauma can cause severe back pain. Intervertebral fusion is a surgical method of alleviating back pain. In intervertebral fusion, two adjacent vertebral bodies are fused together by removing the affected intervertebral disc and inserting an implant that would allow for bone to grow between the two vertebral bodies to bridge the gap left by the disc removal.

A number of different implants and implant materials have been used for fusion with varying success. Current implants used include titanium cages and allografts. Titanium cages suffer from the disadvantage of requiring drilling and tapping of the vertebral endplates for insertion. In addition, the incidence of subsidence in long term use is not known. Due to MRI

incompatibility of titanium, determining fusion is problematic. Finally, restoration of lordosis, i.e., the natural curvature of the cervical and lumbar spine is very difficult when a titanium cage is used.

Allografts are sections of bone taken from the diaphysis of a long bone, such as the radius, ulna, fibula, humerus, tibia, or femur of a donor. A cross section of the bone is taken and processed using known techniques to preserve the allograft until implantation and reduce the risk of an adverse immunological response when implanted. For example, U.S. Patent No. 4,678,470 discloses a method for processing a bone grafting material which uses glutaraldehyde tanning to produce a non-antigenic, biocompatible material. Allografts have mechanical properties which are similar to the mechanical properties of vertebrae even after processing. This prevents stress shielding that occurs with metallic implants. They are also MRI compatible so that fusion can be more accurately ascertained and promote the formation of bone, i.e., osteoconductive. Although the osteoconductive nature of the allograft provides a biological interlocking between the allograft and the vertebrae for long term mechanical strength, initial and short term mechanical strength of the interface between the allograft and the vertebrae are lacking such that there is a possibility of the allograft being expelled after implantation.

U.S. Patent No. 5,728,159 discloses an allograft having grooves on end faces in an attempt to try to promote stability, but there are more effective ways for resisting expulsion.

For example, WO 98/17209, published April 30, 1998, is directed to a spinal spacer and has one embodiment which is an allograft cortical ring having teeth on superior and/or inferior surfaces. These teeth provide the initial, secure interlocking with the vertebrae.

Most allografts are simply sections of bone which, although cut to the approximate height of the disc being replaced, have not been sized and/or machined on the exterior surface to have a uniform shape. As a result, the fusion of the vertebral bodies does not occur in optimal anatomic position in a consistent manner along the surface of the endplates. While a surgeon may do some minimal intraoperative shaping and sizing to customize the allograft for the patient's anatomy, significant shaping and sizing of the allograft is not possible due to the nature of the allograft. Even if extensive shaping and sizing were possible, a surgeon's ability to manually shape and size the allograft to the desired dimensions is severely limited.

As the discussion above illustrates, there is a need for an improved allogenic implant for fusing vertebrae and relieving back pain. The invention as claimed aims at solving the above described problems.

The present invention provides an allogenic intervertebral implant for use when surgical fusion of vertebral bodies is indicated as defined in Claim 1.

The annular plug of allogenic bone is dimensioned in such a way that it conforms in size and shape with end plates of adjacent vertebrae, i.e. a rounded or approximately circular form.

In a preferred embodiment the three-dimensional structure of the intervertebral implant includes a plurality of teeth. Preferably the three-dimensional structure has a minimum height of 0,5 mm and a maximum height of 1,5 mm relative to the top and bottom surfaces of the implant.

The teeth preferably have a pyramid shape or a saw-tooth shape. In one embodiment, the implant has an exterior surface machined to have a uniform shape, such as an oval or a rectangle. The interior space delineated by the annular plug also can have a machined wall to provide the implant with a uniform interior space. The interior space delineated by the annular plug can be filled with spongiosa, bone graft substitutes or artificial bone material.

The top and bottom surfaces may be flat planar surfaces or curved surfaces to mimic the topography of the end plates of the adjacent vertebrae. In a preferred embodiment, the anterior

height of the implant is greater than the posterior height of the implant so that the implant has a wedge-shaped profile to help restore disc height and the natural curvature of the spine.

In one embodiment, the implant has channels on the top and bottom surfaces for receiving a surgical tool, e.g. a distractor. These channels can run in the anterior, lateral, or antero-lateral direction to accommodate a variety of different tools used in surgical procedures. Finally, a threaded hole on the anterior, antero-lateral, or lateral side can be provided for receiving a threaded arm of an insertion tool.

The allogenic bone is preferably in the form of a cross section transverse to the longitudinal axis a human long bone, typically with a height of 5 to 8 mm. Preferably the allogenic bone has been process frozen or freeze dried. The allogenic bone may also be treated with an antiseptic solution.

In the drawings:

FIG. 1 is a top view of a first embodiment of the implant according to the present invention;

FIG. 2 is a front view of the implant of FIG. 1;

FIG. 3 is a top view of a second embodiment of the implant;

FIG. 4 is a side view of the implant of FIG. 1;

FIG. 5 is a side view of a third embodiment of the implant;

FIG. 6 is a close up of region A from FIG. 4 and FIG. 8;

FIG. 7 is a top view of a fourth embodiment of the implant according to the present invention;

FIG. 8 is a side view of the implant of FIG. 7;

FIG. 9 is a top view of a sixth embodiment of the implant; and

FIG. 10 shows an alternative tooth configuration.

FIG. 1 shows a top view of a first embodiment of an allogenic intervertebral implant 10 according to the present invention. Implant 10 is annular and conforms in size and shape with the end plates of the vertebrae between which implant 10 is to be implanted. Because implant 10 is annular, new bone can form in interior 11. Interior 11 can be filled with bone chips or any other osteoconductive material to promote the formation of bone. Although implant 10 will probably be predominantly used in the lumbar region of the spine, implant 10 can be configured for implantation in any region of the spine. Implant 10 has a plurality of teeth 12 on superior and inferior surfaces 14, 16 which provide a mechanical interlock between implant 10 and the end plates. These teeth 12 provide the mechanical interlock by

penetrating the end plates. The initial mechanical stability afforded by teeth 12 minimizes the risk of post-operative expulsion of implant 10. Preferably, teeth 12 are pyramid-shaped in which the angle formed from the tip to the base may be between about 45 and 75° and is preferably about 60°. The details of teeth 12 are best seen in FIG. 6. The teeth provide an enhanced interlock with the adjacent vertebrae compared to the use of channels, because the teeth impale the vertebrae surfaces. In comparison, channels impart grooves into the vertebrae surfaces and the implant can slide out along the direction of the channels or grooves. In an alternative embodiment, teeth 12 have a saw-tooth shape (FIG. 10).

As shown in FIG. 1 and FIG. 2, superior surface 14 has a channel 18 and inferior surface 16 has a channel 20 which is parallel to channel 18. Channels 18, 20 are sized to receive a surgical instrument such as an inserter and/or distractor. As the names imply, an inserter is a surgical instrument used to insert implant 10 and a distractor is a surgical instrument used to separate the adjacent vertebrae so that the surgeon has access to the intervertebral space. If the inserter has a threaded arm, implant 10 can be provided with optional threaded hole 21. In FIG. 1 and FIG. 2, channels 18 and 20 are oriented in the anterior/posterior direction. This orientation is useful if the surgeon prefers an anterior surgical approach.

FIG. 3 shows a second embodiment of an allogenic intervertebral implant 110 according to the present invention. In general, most of the structure of implant 110 (as well as the embodiments described below) is like or comparable to the structure of implant 10 and, accordingly the same reference numeral is used for like components and discussion of those like components is not believed necessary. As shown in FIG. 3, channels 18, 20 can run in the antero-lateral direction to facilitate use of implant 110 with an antero-lateral surgical approach. As another alternative embodiment, channels 18, 20 could run in the lateral direction for a lateral approach. Similarly, a threaded hole 21 optionally can be located on the lateral or antero-lateral side of implant 10.

In order to restore the natural curvature of the spine after the affected disc has been removed, implant 10 is provided with a wedge-shaped profile. As shown in FIG. 4, one way to achieve this wedge shape results from a gradual decrease in height from the anterior side 22 to the posterior side 24. In anatomical terms, the natural curvature of the lumbar spine is referred to as lordosis. When implant 10 is to be used in the lumbar region, angle  $\alpha$  should be approximately  $4,2^\circ$  so that the wedge shape is a lordotic shape which mimics the anatomy of the lumbar spine. Furthermore, when used in the lumbar region, the ratio of the height of anterior side 22 ( $h_1$ ) to the height of posterior side 24 ( $h_2$ ) should be approximately 1,1-2 with the length of implant 10 (l) being approximately 22 - 30 mm.

In FIG. 4, superior and inferior surfaces 14, 16 are flat planar surfaces so that if the surgeon prepares the endplates to be parallel surfaces with a burr, implant 10 fits tightly between the bone surfaces.

FIG. 5 illustrates that superior and inferior surfaces 14, 16 of a third embodiment of an allogenic intervertebral implant 210 can be curved surfaces and still retain the wedge-shaped profile. The curved surface of superior and inferior surfaces 14, 16 is a mirror-image of the topography of the vertebral end plates. Thus, the curved surfaces conform to the contours of the end plates.

FIG. 7 shows a top view of a fourth embodiment of an allogenic intervertebral implant 310 according to the present invention. Although implant 310 will probably be predominantly used in the cervical region of the spine, implant 310 can be configured for implantation in any region of the spine. Interior 11 can be defined by the natural shape of the medullary canal as was the case for implant 10, 110, 210. Alternatively, the medullary canal can be machined so that the wall that formed interior 11 are uniform in shape and texture.

As previously noted, teeth 12 are preferably pyramid-shaped in which the angle formed from the tip to the base is preferably about 60°. Pyramid-shaped teeth help prevent expulsion of the implant in all directions. The prevention of movement between

implant 310 and the vertebrae is particularly important when the surgeon removes all of the annulus fibrosis, as may be the case for cervical vertebrae.

Most allografts are processed and used without significant machining of the exterior surface. In other words, the allografts have substantially the shape of the bone from which the allograft was harvested. As shown in FIG. 7, an exterior surface 26 of implant 310 has been machined to have a uniform shape. The uniform shape promotes initial stability until biological fixation is achieved with bony fusion.

As shown in FIG. 7, the exterior surface 26 has an oval shape. The oval shape preferably is arranged to have lateral sides 28 along the smaller oval axis and anterior and posterior sides 22, 24 along the longer axis. In another embodiment of the invention shown in FIG. 9, the exterior surface 26 of implant 410 is rectangular in shape with lateral sides 28 shorter in length than anterior and posterior sides 22, 24. The oval and rectangle shape and size of implants 310, 410 can be made to closely match the shape and size of the affected vertebrae. Typically, lateral sides 28 and anterior and posterior sides 22, 24 would be approximately 8-18 mm in length.

In order to restore the intervertebral space to the proper size after the affected disc has been removed, implant 310 has a height, h, sized to match the height of the removed disc, as shown in FIG. 8. The matched height helps promote fusion by

providing direct contact between the bone and implant 310. Typically, h would be approximately 4-20 mm for cervical vertebrae. Implant 310 has a uniform height so that the profile of implant 310 is rectangular. Alternatively, as shown in FIG. 4 and FIG. 5, implant 310 can have a wedge shaped profile with either flat planar surfaces or curved surfaces.

It should be noted that implants 310, 410 can be configured so that h would be approximately 10-100 mm. These larger sizes could be used in corpectomy, a surgical procedure in which a section of several vertebrae is removed. Implants 310, 410 would be inserted in the space created by the removed section of bone. Due to the nature of corpectomy, an accurate preoperative determination of the size of the implant needed is not possible. Thus, implant 310, 410 can be cut to the proper size by the surgeon. In such cases, the implants 310, 410 would only have teeth on either superior surface 14 or inferior surface 16.

## CLAIMS

1. Intervertebral implant (10) comprising an annular plug of allogenic bone conforming in size and shape with end plates of vertebrae, wherein top and bottom surfaces (14,16) of the implant (10) include a three-dimensional structure (12) positioned thereon for interlocking with adjacent vertebrae.
2. Intervertebral implant (10) according to claim 1, wherein said three-dimensional structure (12) includes a plurality of teeth.
3. Intervertebral implant (10) according to claim 1 or 2, wherein said three-dimensional structure (12) has a minimum height of 0,5 mm relative to the top and bottom surfaces (14,16).
4. Intervertebral implant (10) according to one of the claims 1 to 3, wherein said three-dimensional structure (12) has a maximum height of 1,5 mm relative to the top and bottom surfaces (14,16).
5. Intervertebral implant (10) according to one of the claims 1 to 4, wherein said allogenic bone has been obtained from a human long bone, preferably from a femur, humerus, radius, ulna or fibula.
6. Intervertebral implant (10) according to claim 5, wherein said allogenic bone is a cross section transverse to the longitudinal axis of said long bone, preferably with a height of 5 to 8 mm.

7. Intervertebral implant (10) according to one of the claims 1 to 6, wherein said allogenic bone is treated with an antiseptic solution.
8. Intervertebral implant (10) according to one of the claims 1 to 7, wherein said allogenic bone has been process frozen or freeze dried.
9. Intervertebral implant (10) according to one of the claims 1 to 8, wherein the allogenic bone comprises glutaraldehyde.
10. Intervertebral implant (10) according to one of the claims 1 to 9, wherein the interior space delineated by the annular plug is filled with spongiosa, bone graft substitutes or artificial bone material.
11. Intervertebral implant (10) according to one of the claims 1 to 10, wherein the top and bottom (14,16) surfaces each have a channel (18,20) for receiving a surgical instrument.
12. Intervertebral implant (10) according to claim 11, wherein the channels (18,20) run in an anterior-posterior direction.
13. Intervertebral implant (10) according to claim 11, wherein the channels (18,20) run in an antero-lateral direction.
14. Intervertebral implant (10) according to claim 11, wherein the channels (18,20) run in a lateral direction.

15. Intervertebral implant (10) according to one of the claims 1 to 14, wherein the implant has a wedge-shaped profile to help restore disc height and spine curvature.

16. Intervertebral implant (10) according to claim 15, wherein said implant has an anterior height which is greater than a posterior height to produce the wedge-shaped profile.

17. Intervertebral implant (10) according to one of the claims 1 to 16, wherein the teeth (12) have a pyramidal shape.

18. Intervertebral implant (10) according to one of the claims 1 to 17, wherein at least one side of the implant (10) has at least one hole for attachment of an inserter.

19. Intervertebral implant (10) according to claim 18, wherein the at least one hole is threaded.

20. Intervertebral implant (10) according to claim 19, wherein the at least one hole is provided in an anterior, antero-lateral, or lateral side.

21. Intervertebral implant (10) according to one of the claims 1 to 20, wherein the top and bottom surfaces (14,16) are flat planar surfaces.

22. Intervertebral implant (10) according to one of the claims 1 to 20, wherein the top and bottom surfaces (14,16) are curved surfaces which are contoured to mimic the end plates of the adjacent vertebrae.

23. Intervertebral implant (10) according to one of the claims 1 to 22, wherein the exterior surface of said implant has a uniform shape.

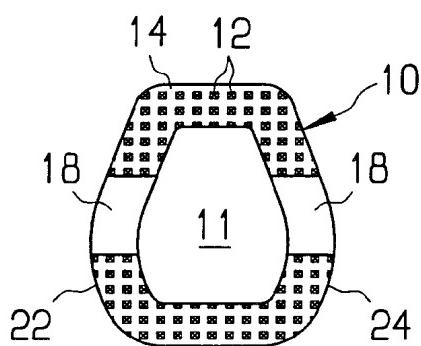
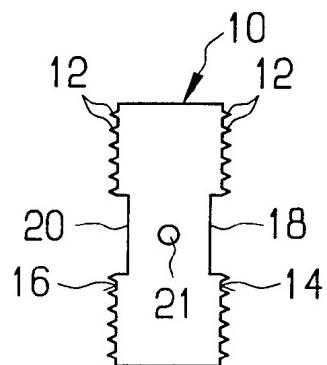
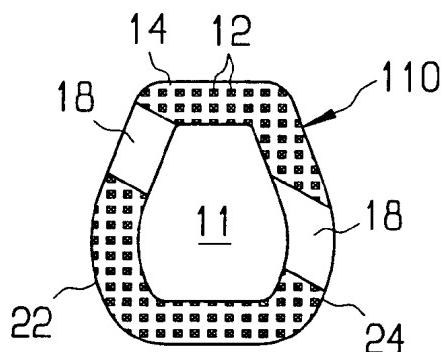
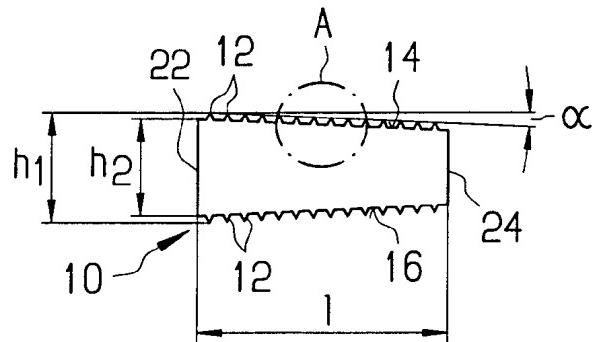
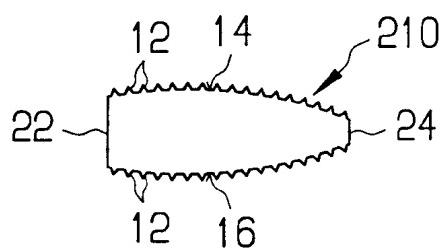
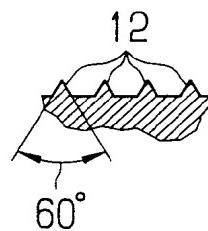
24. Intervertebral implant (10) according to claim 23, wherein the exterior surface has an oval shape.

25. Intervertebral implant (10) according to claim 23, wherein the exterior surface has a rectangular shape.

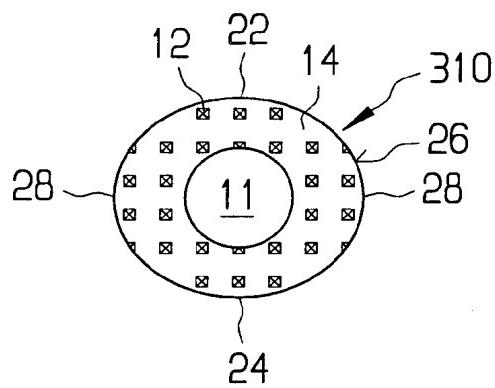
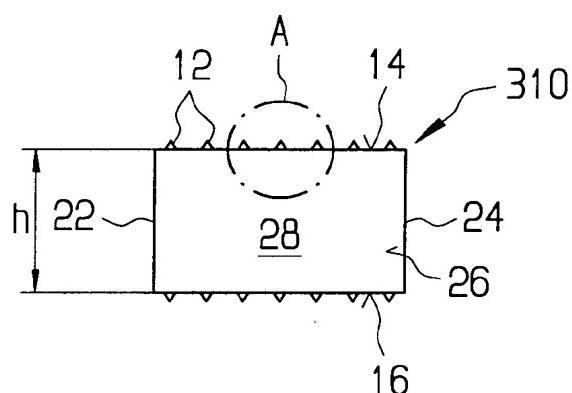
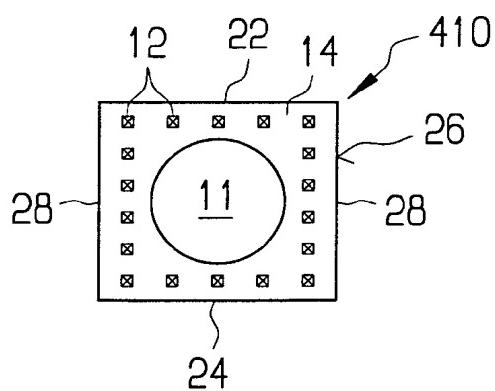
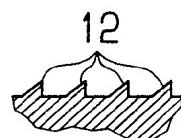
26. Intervertebral implant (10) according to one of the claims 1 to 25, wherein the annular plug includes an interior surface of a machined wall.

27. Intervertebral implant (10) according to one of the claims 1 to 26, wherein, the teeth have a saw tooth shape.

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**FIG. 1****FIG. 2****FIG. 3****FIG. 4****FIG. 5****FIG. 6**

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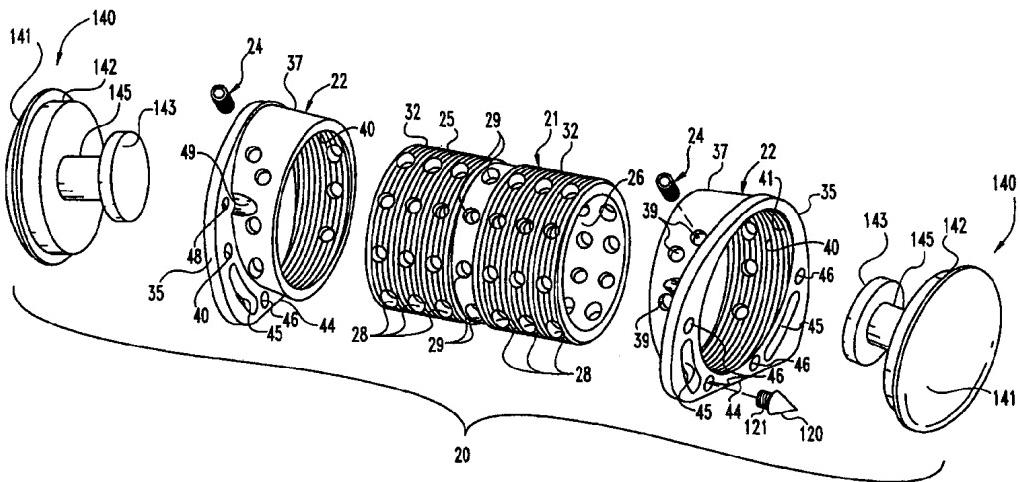
**FIG. 7****FIG. 8****FIG. 9****FIG. 10**



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(54) Title: ADJUSTABLE VERTEBRAL BODY REPLACEMENT



## (57) Abstract

An adjustable vertebral body replacement implant and assembly includes a thin-walled cylindrical body configured to span over most of the length between intact vertebrae when damaged or diseased vertebrae have been removed. The cylindrical body defines a hollow interior and includes endplates with end surfaces configured to contact the adjacent vertebra and to engage the cylindrical body therebetween. Said end surface includes a blade or plurality of blades configured to penetrate the adjacent vertebra and to facilitate insertion and removal of the implant. This end surface also defines a bore through said endplate. In one embodiment, an end cap which includes a porous body such as porous tantalum manufactured under the name HEDROCEL® is placed in said bore. The end cap provides strength to carry the vertebral loading while allowing vascularization between the intact vertebral and bone growth material disposed within the implant. In another embodiment, the end cap includes an anchor embedded in the bone growth material. The end cap may also include a positioning surface to align the end cap within the bore.

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## ADJUSTABLE VERTEBRAL BODY REPLACEMENT

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### BACKGROUND OF THE INVENTION

The present application is a continuation-in-part of U. S. Patent Application No. 08/647,272 filed on May 13, 1996, which is a file-wrapper-continuation of U.S. Patent Application No. 08/353,566 filed on December 9, 1994.

10 The present invention concerns an implant for replacement of one or more vertebral bodies and their adjacent disks. More particularly, the vertebral body replacement is particularly well suited for implantation through an anterior approach.

The treatment of injuries to the spine has advanced significantly since the days of the first recorded surgical procedure for spinal cord injury in the late 7th Century.

15 The techniques, instrumentation and implants have changed over the years and have been better adapted to address many forms of spinal injury and deformities that can occur due to trauma, disease or congenital effects. One type of spinal deformity, a kyphosis, involves a prolapse of the vertebral column towards the front of the body, often caused by the destruction of the vertebral body itself. This destruction can be 20 in the form of a trauma type injury, such as a fracture or burst injury to the vertebral body, or a non-traumatic deformity caused by a tumor or a degeneration of the bone in the vertebral body.

Treatment of a kyphosis in the thoracic or lumbar spine appears now to be best achieved through an anterior approach, particularly in order to avoid some of the 25 more severe complications associated with support or replacement of a damaged vertebral body. In most treatments of a kyphosis, a high degree of anterior reconstruction of the spine is required, most frequently involving total removal of the damaged vertebral body. In a typical anterior approach, partial or total ablation of the vertebral body and the two adjacent vertebral disks is carried out. The 30 remaining space is then distract ed to manipulate the spine to its correct orientation.

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In many cases, the space is filled with a polymerizable paste or a bone graft which is frequently modeled to give it the shape of the destroyed vertebral body. Frequently, autologous bone, such as that extracted from the ilium, is used to bridge the space. The polymerizable paste can include a PMMA bone cement. Once the cavity remaining after the removal of the original vertebral body has been filled, an osteosynthesis instrument is positioned between the adjacent unaffected vertebrae to prevent any relative movement therebetween. The osteosynthesis device is essential to restabilize the vertebral column, to support the loads to which the thoracic or lumbar spine is exposed, and to enhance the likelihood and quickness of union of the bone graft material with the adjacent vertebral bodies. Once the bone graft and material is sufficiently solid, the osteosynthesis device normally is not subjected to any further mechanical stresses.

A known osteosynthesis device is depicted in U.S. Patent No. 5,108,395 to Jean-Marie Laurain, the disclosure of which is incorporated herein by reference. This system is illustrated in FIGS. 1 and 2 of the present application. Referring first to FIG. 1, it can be seen that a damaged vertebra V<sub>3</sub> includes a destroyed vertebral body C<sub>3</sub>. An interior implant 1 is provided for bridging between the two intact vertebrae V<sub>2</sub> and V<sub>4</sub> to permit removal of the damaged vertebra V<sub>3</sub> and its adjacent disks D<sub>2</sub> and D<sub>3</sub>. The anterior implant 1 includes a pair of clamps 2 which are engaged to the intact vertebral bodies by way of a number of spikes 3. In addition, the clamps 2 are maintained in position by bone screws 5 extending through screw holes 11, lateral lugs 8 of the clamps. The implant 1 also includes a plate 6 which is configured to span between the intact vertebrae and is strong enough to support the loads generated in the spinal column at that location.

Each clamp 2 includes a threaded post 12 projecting therefrom which is configured to pass through a corresponding opening 14 at each end of the plate 6. A nut 7 is adapted to engage the threaded post 12 to fix the plate 6 to each of the clamps 2. The surface of the clamps 2 include serrations 15 which mate with corresponding serrations 16 at each end of the plate 6, thereby permitting differing

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angular orientations of the plate relative to each of the clamps. An opening 9 is provided through the threaded post 12 of the clamps to receive another bone screw 5 for firm fixation of the clamp with the healthy vertebral bodies V<sub>2</sub> and V<sub>4</sub>.

An important feature of the system described in the '395 patent is the provision  
5 of notches 18 in each of the clamps 2. The notches are configured to receive the tips  
of a forceps 19 which is used to provide a distraction force between the two  
vertebrae V<sub>2</sub> and V<sub>4</sub>. As shown in FIG. 2, once the clamps 2 are fixed to the  
corresponding intact vertebrae, the forceps 19 are used to distract and permit room  
for placement of a bone graft G. Once the bone graft is in place, the anterior plate 6  
10 can be attached to each of the clamps 2 in the manner previously described. Once  
the plate is in position, the distraction forceps 19 is removed and the nut 7 tightened  
to form a rigid construct.

The anterior construct shown in the '395 patent and in FIGS. 1 and 2 of this  
application is one system for providing anterior fixation with the use of autologous  
15 or allogenic bone graft material. Other implants have been devised which rely upon  
an additional element interposed between the adjacent vertebra, in lieu of or in  
addition to the traditional bone graft material. One such device is shown in the  
patent to Harms et al. no. 4,820,305, which is sold as the "Harms Cage" by the  
Biedermann-Motech Company. This device contemplates a hollow cylindrical mesh  
20 which is inserted in the gap between adjacent vertebra, with bone graft material  
being disposed inside the hollow interior of the mesh.

The patent to Brantigan, No. 5,192,327, shows a device similar to the "Harms  
Cage" which is composed of a number of hollow oval-shaped implants within which  
bone graft material is disposed. European Patent No. 0 179 695 to Kehr shows a  
25 rigid inert body having a number of passageways extending between the intact  
vertebrae into which bone growth material can be implanted. In addition, the device  
shown in the Kehr European patent includes a plate spanning between the vertebrae  
having holes for receiving bone screws therethrough.

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Another variety of implant devices particularly suited for replacement of vertebral bodies include components of generally solid construction which completely occupy the empty vertebral space. These devices are represented by the patents to Kapp et al., no. 4,554,914; Doty, no. 4,599,086; Ogilvie et al., no. 5. 4,636,217; and Downey, no. 5,147,404. Each of these devices is provided with a spike or similar mechanism for engaging the endplates of the intact vertebrae to maintain the implant in position. A similar construction is followed in the U.S. Patent 5,062,850 to MacMillan et al., although this device includes open space between support columns of the axially fixed vertebral body prosthesis.

In each of the former patents, the implant device requires separate distraction of the intact vertebrae prior to insertion of the device. The following patents show vertebral prostheses which include some feature for expansion of the device in situ. For example, the Main et al., no. 4,932,975, and Barber no. 5,236,460 show prostheses that telescope through the admission of a hydraulic fluid. The patents of Rezaian, no. 4,401,112; Wu, no. 4,553,273 and Daher, no. 4,657,550 show devices that expand in situ the manipulation of a threaded component. In addition, the Rezaian patent shows a turnbuckle construct of this type with the addition of a spiked plate engaged in the opposite intact vertebrae to strengthen the construct.

In recent years, the application of anterior approaches to instrumenting the spine has become more prevalent. As these anterior approaches advance, it becomes of greater necessity to provide a vertebral body replacement that meets all of the benefits of anterior surgery without the detriments of the several prior devices. Each of the above-mentioned vertebral body replacements suffer from one or more disadvantages. For instance, some of the devices do not provide means for osteosynthesis between the intact vertebrae. These devices lack features that can either permit bone ingrowth or facilitate placement of bone graft between adjacent healthy vertebrae. It is recognized that a more permanent and stable correction of a kyphotic condition occurs with fusion of a bony mass in place of the replaced vertebra. Thus, any vertebral body replacement should accommodate this aspect.

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Other vertebral prostheses offer no means for adjusting the size of the implant to accommodate the specific vertebral anatomy. Further, other of the devices do not contemplate some auxiliary fixation to help provide a stable construct. Each of these needs, and many others, are met by the vertebral body replacement according to the  
5 present invention.

## SUMMARY OF INVENTION

The present invention contemplates a vertebral replacement implant and assembly for fixation of the implant in the space left by a removed vertebra between 5 two intact vertebrae. In one aspect, the implant includes a thin-walled cylindrical body sized to occupy a substantial portion of the space between the intact vertebrae. The cylindrical body is hollow with a plurality of apertures through the wall of the body in communication with the interior, to permit bone ingrowth once the implant is implanted. The opposite ends of the cylindrical body carries continuous threads, 10 preferably on the outer surface of the body.

The inventive implant further contemplates a pair of endplates having a surface directed against a corresponding one of the intact vertebrae when the prosthesis is implanted. The endplates each include a cylindrical portion extending from the end surface, which portion includes threads for mating with the threaded ends of the 15 cylindrical body. Preferably, the threads of the endplates are internal to the cylindrical portion. In one aspect, the endplates are themselves hollow to provide communication between the hollow interior of the cylindrical body and the adjacent intact vertebrae. Alternatively, the invention contemplates the addition of an end cap to the implant to close the end surface of the endplates against the adjacent vertebrae 20 in order to provide additional support for weak vertebrae.

In another embodiment, the end cap is formed with a porous material such as 25 porous tantalum provided under the name HEDROCEL® by Implex Corporation. The end cap may also include a positioning surface to align the end cap in the endplate opening. In another embodiment, the end cap includes an anchor projecting into the hollow interior of the implant to resist dislodgment.

Another inventive aspect resides in the means for fixing the implant to adjacent 30 intact vertebrae. In one embodiment, the means for fixing includes spikes which are integrally attached or threadedly engaged to the endplate. Alternatively, the means for fixing the implant includes blades integrally attached to the endplate.

Another feature of the invention resides in the provision of means for fixing the cylindrical body to each of the endplates to prevent unthreading of the mating threads of the three components of the implant. In one embodiment, the means for fixing includes apertures in the threaded portion of the endplates which are threaded 5 to accept a set screw. Preferably, two set screws are threaded into two such apertures in the endplates to apply a clamping pressure against the cylindrical body engaged with the endplate.

In another embodiment, the means for fixing contemplates a crimpable cylindrical portion of the endplates. In one aspect, the cylindrical portion includes 10 an annular ring, dissected by a crimping notch. The application of a crimping force around the annular ring reduces the notch, and thereby reduces the circumference of the cylindrical portion so it is tightly engaged about the cylindrical body threaded therein.

Another inventive aspect resides in the provision of means for connecting the 15 implant to a longitudinal member extending outside the space left by the removed vertebrae. The longitudinal member may be a plate or a rod that is fixed in a known manner to the adjacent intact vertebrae. Preferably, the longitudinal member can be used to assist in the distraction of the intact vertebrae for insertion of the vertebral replacement implant.

20 In one embodiment, the means for connecting includes a clamp configured to clamp onto the longitudinal member. The clamp supports a screw directed towards the replacement implant when it is interposed between the intact vertebrae. The cylindrical body of the implant includes a number of apertures threaded to receive the connecting screw. The clamp is preferably slidable along the length of the 25 longitudinal implant to facilitate alignment of the screw with the number of threaded apertures of the cylindrical body. In addition, the clamp includes a spherical seat, and the screw includes a spherical head to permit varying angular orientations of the screw relative to the longitudinal member.

In another embodiment, the means for connecting includes an arm extending from a flange of the endplates. The free end of the arm defines an opening through which the longitudinal member extends. A set screw intersects the opening to provide fixation of the longitudinal member to the arm of the endplates.

5 One object of the present invention is to provide a vertebral body replacement implant configured to support the space left by removal of a damaged or diseased vertebra. One objective is to provide an implant that can be easily adjusted to vary the overall length of the implant dependent upon the vertebral level into which the implant is interposed. A further objective of the inventive implant is to permit this  
10 length adjustment yet provide means for fixing the components to prevent disengagement or unthreading.

A further object is achieved by the present invention by the provision of means for connecting the vertebral replacement implant to a longitudinal member extending along the length of the spine between the adjacent intact vertebrae. The longitudinal  
15 member can be used for distracting the space left by the removed vertebra to facilitate insertion of the replacement implant. Yet another object is to provide an implant that can house bone growth material to facilitate fusion of the instrumented level and promote vascularization between adjacent intact vertebrae and the bone growth material in the implant.

20 One benefit of the vertebral body replacement of the present invention is that it provides a strong implant to support the spinal loads while awaiting fusion of bone growth material between the intact vertebrae. A further benefit is that the implant can be more easily adjusted to accommodate spaces at different vertebral levels. Another benefit is that the implant provides a means for fixation to the existing intact  
25 vertebrae when the implant is implanted to prevent disengagement.

Other objects and benefits of the invention can be gleaned from the following written description of the invention, considered together with the accompanying figures and claims.

## DESCRIPTION OF THE FIGURES

FIG. 1 is an exploded perspective view of a spinal osteosynthesis implant according to the prior art patent 5,108,395.

5 FIG. 2 is a view showing a portion of the view of FIG. 1 with the addition of an instrument for permitting positioning of a graft between the vertebrae carrying the clamps associated with the prior device of the '395 patent.

FIG. 3 is an exploded perspective view of a vertebral body replacement assembly in accordance with one embodiment of the present invention.

10 FIG. 4 is an end elevational view of an endplate used in connection with the vertebral body replacement assembly shown in FIG. 3.

FIG. 5 is a side elevational view of an endplate used with the vertebral body replacement assembly of FIG. 3.

15 FIG. 6 is a perspective exploded view showing a component of the clamp assembly used with the vertebral body replacement assembly shown in FIG. 3.

FIG. 7 is a side elevational view of a vertebral body replacement assembly in accordance with another embodiment of the invention, particularly for use with an elongated rod spanning the vertebral sections.

20 FIG. 8 is an end elevational view of the vertebral body replacement assembly shown in FIG. 7, with the assembly shown in position on a intact vertebra.

FIG. 9 is a side elevational view of the assembly shown in FIG. 7 as engaged to an elongated rod.

FIG. 10 is a perspective view of the endplate used with the vertebral body replacement assembly shown in FIG. 7.

25 FIG. 11 is an end elevational view of one specific endplate used in connection with the vertebral body replacement assembly shown in FIG. 3 in the thoracic spine.

FIG. 12 is a perspective view of a porous end cap used with the endplate shown in FIGS. 10 and 11.

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FIG. 13 is a side elevational view of the porous end cap embedded in the implant.

FIG. 14 is a perspective view of the vertebral body replacement endplate with blades in lieu of spikes as shown in FIGS. 3 and 7.

## DESCRIPTION OF THE PREFERRED EMBODIMENTS

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiments illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is thereby intended, such alterations and further modifications in the illustrated device, and such further applications of the principles of the invention as illustrated therein being contemplated as would normally occur to one skilled in the art to which the invention relates.

Referring now to FIG. 3, a vertebral body replacement assembly 20 is shown in accordance with one embodiment of the present invention. The assembly 20 generally includes a threaded cylindrical body 21, threaded endplates 22 and end caps 23. A set screw 24 is also provided as one embodiment of a means for fixing each of the endplates 22 to a corresponding end of the cylindrical body 21. In one specific embodiment, the set screw 24 is a breakable locking screw in which the head of the screw shears off when the tightening torque limit is reached. Such a locking screw is disclosed in co-pending French patent application No. 94 10 377, filed on August 29, 1994.

The threaded cylindrical body 21 is formed from a cylindrical wall 25 which defines a hollow cavity 26 therein. The cavity is configured to receive bone osteosynthesis material, which may be in the form of autogenous or allograph material. The cylindrical wall 25 is provided with a plurality of apertures 28 in communication with the cavity 26. These apertures provide a path for bone or tissue ingrowth to further enhance the stability of the implant. The cylindrical wall 25 includes a second plurality of threaded apertures 29 generally in the middle of the implant, which are configured to engage the support assembly 55 as described in more detail herein.

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- In one important feature of the cylindrical body 21, the opposite ends of the cylindrical wall 25 are formed into external threads 32. In one specific embodiment, the threads 32 extend from each opposite end over most of the total length of the threaded cylindrical body 21 and are configured to engage the threaded endplates 22.
- 5    Each endplate includes a flange 35, which preferably assumes a shape to cover a substantial load-bearing area of the endplates of the adjacent intact vertebral bodies. A cylinder 37 is integrally formed with flange 35 to extend toward the threaded cylindrical body 21 when the endplates 22 are placed within the excised vertebral space. The cylinder 37 of each endplate includes a number of threaded openings 39 adapted to receive a set screw 24 therein.
- 10   The cylinder 37 and flange 35 of the endplates 22 define a bore 40 therethrough. The inside surface of the bore 40 is provided with internal threads 41 which are configured to mate with the external threads 32 of the cylindrical body 21. In the preferred embodiment, the threads 41 extend along at least the entire length of the cylinder 37 and preferably into the flange 35.
- 15   Further details of the endplates 22 can be seen in FIGS. 4 and 5. As shown in FIG. 5, the cylinder 37 is integrally formed with the flange 35 to define a lordosis angle 43. This angle is intended to permit use of the vertebral body replacement assembly 20 to replace a damaged vertebra, such as vertebra V<sub>3</sub> shown in FIG. 1, and still maintain the normal lordotic curvature of the spine at that level. The end face 36 of the flange 35 is provided with vascularization apertures 45 extending through the flange. These apertures 45 are intended to provide an avenue for vascularization of the space between the adjacent vertebrae. The end face 36 can be provided with four spikes, such as spikes 91 shown in the embodiment of FIG. 7.
- 20   Alternatively, spikes 120 (FIG. 3) can be provided that include a threaded stem 121 to be engaged in threaded apertures 46 defined in end face 36.
- 25   In another embodiment, spikes 91 and 120 are replaced by a plurality of blades 130 as shown in FIG. 14. The blades are preferably integrally attached to end face 36. Each blade is wedge-shaped with flat surfaces 131 engaged to end face 36 and

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with a cutting edge 132 projecting outwardly to penetrate an adjacent vertebral surface. Blades 130 provide for easier insertion of the implant between two adjacent intact vertebrae. Blades 130 also enhance the stability of the interface between the vertebrae by securing the implant to the intact vertebrae when the implant is  
5 inserted.

The end face is further provided with a mounting slot 47 passing across the flange 35 and spanning along a chord of the internal bore 40. Within each mounting slot is an aperture 48 passing therethrough. The cylinder 37 of the endplate 22 is provided with a mounting notch 49 that is aligned with each aperture 48 in the  
10 mounting slot 47. This slot 47, aperture 48 and notch 49 are configured to support an end cap 23, as herein described. Referring back to FIG. 3, the end cap 23 includes a generally rectangular support bar 50 which is mounted to span across a chord of the flat circular plate 52 of the end cap. At each end of the support bar 50 is an outwardly projecting lug 51. Each lug 51 is sized to be received within a  
15 corresponding aperture 48, while the support bar 50 is itself configured to fit within the mounting slot 47 in the flange 35. Further, each lug 51 slides conveniently into a corresponding mounting notch 49 in the cylinder 37. In this manner, the end cap 23 is held in position, particularly when the replacement body assembly is disposed between the adjacent intact vertebrae V<sub>2</sub> and V<sub>4</sub>.

20 The end cap 23 provides additional support for the implant between the adjacent intact vertebrae. The end cap can be eliminated if bone growth between the adjacent vertebrae and through the replacement body is preferred. Alternatively, the plate 52 of each end cap 23 can be perforated to permit bone ingrowth between the vertebral endplates and the bone growth material disposed within the threaded cylindrical body  
25 21. In one embodiment, the endplates are shown solid to provide the maximum load bearing capability for loads along the length of the vertebral column.

In another embodiment shown in FIGS. 12 and 13, end cap 140 is formed of a porous material such as a porous tantalum provided under the name HEDROCEL® by Implex Corporation. The HEDROCEL® material includes an open cell structure

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formed by chemical vapor deposition of tantalum onto a reticulated carbon foam substrate. The porous end cap 140 includes a plurality of internally interconnected interstices, which can permit tissue or bone growth entirely through the end cap. A structure is created that is lightweight, strong and porous. The structure also mimics the natural cancellous bone and allows bone ingrowth between the intact vertebrae and the bone growth material disposed within the implant. The HEDROCEL® material also provides the necessary strength to support vertebral loads. Other porous material may also be used for end cap 140 provided they have the necessary strength and allow ingrowth between the intact vertebrae and the bone growth material in the implant. The material can preferably be fully integrated into the resulting bone growth.

End cap 140 includes contact surface 141 (FIG. 12) for contacting the intact vertebra when the implant is placed in the space left by one or more removed vertebrae. Preferably, the contact surface 141 is slightly convex to conform to the slight concavity of the vertebral endplates. End cap 140 can further be provided with positioning surface 142 to align the end cap within bore 40 of end face 36 as shown in FIG. 12. In another feature, the end cap 140 can include an anchor 143 projecting from the interior face of the end cap. As shown in FIG. 13, anchor 143 can be embedded in bone growth material 144 to provide stability to the end cap when anchor 143 is placed in bore 40 as the implant is inserted in the space left by one or more removed vertebrae. Anchor 143 also resists dislodgment of the end cap from the device 20 prior to implantation.

In one specific embodiment, end cap 140 includes a stem 145 projecting away from contact surface 141. Anchor 143 can be integrally attached to stem 145. In the specific embodiment, stem 145 can have a diameter approximately one-half of the diameter of anchor 143. Anchor 143 can have a diameter approximately one-half of the diameter of thread cylindrical body 21. This allows anchor 143 to be inserted into device 20 without total displacement of bone growth material 144 from the interior of end plate 22. Other structures which secure end cap 40 to end plate 22

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are also contemplated. One embodiment can include a stem that is tapered with the larger end of the stem disposed within the implant. Another embodiment may contemplate a stem with outward protrusions into the bone growth material. These embodiments could be configured to achieve the same desired result as the specific  
5 embodiment.

In the illustrated embodiment, the threads 32 on the cylindrical replacement body are external threads, while the threads 40 in the endplates are internal. Alternatively, the cylinder 37 of the endplates can carry external threads and the cylindrical replacement body carry internal threads in the cavity 26. In this latter  
10 instance, the inner diameter of the cylindrical body would naturally be slightly greater than the outer diameter of the cylinder of the endplates.

In the preferred embodiment, the cylindrical wall forming the implant 21 can be relatively thin, when compared against replacement bodies of the prior art. In one specific embodiment, the wall is one (1) mm. thick. Since the primary load endured  
15 by the implant will be axial compression, rather than bending, a thin-walled cylinder is appropriate and even desirable.

It is also preferred that the implant 21 include a large number of apertures 28, 29 to promote tissue ingrowth and vascularization, thereby enhancing the stability of the construct after fusion has occurred. In one specific embodiment, the total area of  
20 the plurality of apertures is at least twenty five percent (25%) of the surface area of the cylindrical body 21.

In use, the damaged vertebra, such as vertebra V<sub>3</sub> shown in FIG. 1, is removed. In one embodiment, the clamps 2 of the interior implant 1 shown in FIGS. 1 and 2 are engaged to the intact vertebral bodies in the manner shown in  
25 FIG. 2. Also shown in FIG. 2, the forceps 19 can be used to distract the intact vertebrae to permit implantation of a vertebral body replacement assembly 20. In the preferred method, the optimum vertebral height is determined and the threaded cylindrical body 21 and threaded endplates 22 are fitted together to achieve that

proper height. Specifically, each of the end caps can be threaded onto the threaded cylindrical body 21 until the desired height is attained.

It is important that the bottom edge 44 of the flange 35 of each of the endplates be generally oriented in the same way between the two threaded endplates 22. This orientation is important because the replacement assembly 20 will be disposed between the two intact vertebrae, bearing against the endplates of those vertebrae. In order to maintain the maximum load bearing capability, the flanges 35, and particularly the end face 36, assume the shape of the vertebral body against which the endplates bear and are sized to occupy as much area of the intact vertebral body end plate as possible.

Preferably, three such shapes are provided to accommodate the anatomic variations of the vertebral bodies at the lumbar, thoraco-lumbar and thoracic levels. the configuration of the flange 35 shown in FIG. 4 is applicable to the thoraco-lumbar vertebrae. A smaller, more rounded, configuration can be provided for implantation at the thoracic level, such as the flange 35' shown in FIG. 11. The flange 35' is also shown as including a relief radius 38 to increase the clearance between the flange and the dural space housing the spinal cord. This relief radius 38 is preferably included in all three shapes of the endplate flanges.

In one specific embodiment, the external threads 32 on the threaded cylindrical body 21 are cut in opposite directions so that the endplates can be drawn together or apart by rotating only the cylinder. Thus, as the cylinder is rotated in one direction, the threads 32 at each of the ends engage the internal threads 41 of each of the end caps 23 in the right direction to draw the end caps together. Alternatively, the handedness of the threads 32 can be the same at each end so that it is necessary to individually thread each end cap in opposite directions onto the cylindrical body 21. The disadvantage of this arrangement is that it is more difficult to adjust the height of the total assembly 20 while maintaining the proper orientation of each of the lower edges 44 of the end face 36. An advantage is that in situ the assembly is unable to unthread itself.

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Once the endplates and threaded cylindrical body have been engaged in the proper orientation for the correct height, the set screws 24 are threaded into an appropriate one of the threaded openings 39 in the cylinder 37 of the endplates 22, in order that the set screw 24 extend into contact with the threaded cylindrical body  
5 21. The set screws 24 (which can be the breakable locking screws mentioned above) exert a clamping pressure against the body 21 to hold it in place. Thus, the set screws 24 provide a means for fixing the components together and prevent rotation of the cylindrical body 21 with respect to either of the endplates 22. Preferably, two set screws are used at each endplate 23 to firmly fix the associated ends of the  
10 threaded cylindrical body 21. To ensure that the set screws 24 achieve firm purchase on the body 21, the apertures 28 in the threaded body have a smaller diameter than the set screws 24.

With the cylinder and endplates thus fixed at their proper height dimension, bone graft material can then be inserted into the bore 40 of the endplates and cavity  
15 26 of the cylindrical body 21. After the interior of these components has been completely filled with bone graft material, the endplates 23 are placed in position with the lugs 51 extending through apertures 48, and with support bar 50 passing through mounting slot 47 in each endplate. The replacement assembly 20 can then be disposed between the distracted vertebrae V<sub>2</sub> and V<sub>4</sub>. Once the assembly is  
20 properly positioned with the end faces 36 of each of the endplates 22 properly oriented on the vertebral endplates, the distraction forceps 19 are removed so that the assembly 20 is clamped in place between the two vertebrae.

In order to further ensure that the replacement assembly 20 will not migrate or slip in its position between the intact vertebrae, a support assembly 55 may be  
25 provided. In the preferred embodiment, this support assembly 55 is configured to mate with the clamps 2 used with the anterior implant system of the prior art shown in FIGS. 1 and 2. The support assembly 55 can also be used with other anterior plates, such as the Z-PLATE ATL\* sold by Danek Medical, Inc., or rod systems such as the CD Hopf System of Sofamor, S.N.C.

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In particular, the support assembly includes a stabilization plate 57, which can be configured substantially similar to the plate 6 shown in FIG. 1, including the serrations on the bottom face of the ends of the plate. Means for connecting the vertebral replacement body assembly 20 to the plate 57 includes a clamp assembly 59 is provided which firmly grips the plate 57 to support a locking screw 69. The clamp assembly 59 includes a pair of clamp halves 60 which are preferably in the shape of a C to grip and support the plate 57. Each of the clamp halves 60 include an aperture (not shown) which receives a threaded rod 63 of an adjustment plate 62. A nut 64 is threaded on the rod 63 to draw the clamp halves 60 together about the stabilization plate 57.

The details of the adjustment plate 62 are shown more clearly in FIG. 6. The adjustment plate includes the threaded rod 63 extending from a face 65 of the plate 62. The plate 62 also includes an aperture 67 therethrough having a spherical seat surface 68 into which a corresponding spherical head 70 of the locking screw 69 is received. The locking screw 69 includes a hex recess 71 in its head to accept a driving tool. The locking screw 69 also includes a threaded shank 73 which is adapted to engage one of the threaded apertures 29 in the threaded cylindrical body 21. To help guide the locking screw 69 into position, a guide nub 75 is provided having a smaller diameter than the threaded shank 73. The locking screw 69 preferably includes smooth shank 74 between the head 70 of the screw and the threaded shank 73.

In use, the clamp halves 60 can be tentatively attached but not clamped to the stabilization plate 57. The stabilization plate 57 can then be engaged to the clamps 2 in each of the intact vertebral bodies and fixed in place by a corresponding nut, such as nut 7 shown in FIG. 1. With the stabilization plate 57 thus attached between the distracted vertebrae, the distraction forceps 19 can be removed so that the full load of the spinal column can be borne by the replacement assembly 20. Once the distraction forceps have been removed, the clamp halves 60 can be adjusted along the length of the plate 57 so that the locking screw 69 is aligned with an appropriate

one of the threaded apertures 29 in the threaded cylindrical body 21. The spherical contact between the head 70 of the locking screw 69 and the spherical seat 68 of the adjustment plate 62 allows the locking screw to assume whatever angle is necessary to engage a threaded aperture 29. As so aligned, the locking screw 69 can then be  
5 easily threaded into one of the apertures 29 until it is locked between the adjustment plate 62 and the threaded cylindrical body 21. At this point then, the clamp halves 60 can be fully clamped onto the plate 57 by tightening the nut 64 on the threaded rod 63.

In another embodiment of the invention, a vertebral body replacement assembly  
10 80 is configured for connection to an elongated distraction or compression rod. In this embodiment, the assembly 80 includes opposite endplates 83 which are configured to threadedly engage a cylindrical body 21. (This cylindrical body 21 is substantially identical in all respects to the cylindrical body 21 described with respect to FIG. 3). With this embodiment, the endplates 83 include a flange 85 and  
15 a cylinder 87 projecting therefrom. The cylinder 87 includes a threaded bore 88 which is threaded to accept the external threads 32 of the cylindrical body 21. Like the prior endplates, the endplate 83 includes a plurality of vascularization apertures 89 formed through the flange 85. The end face 86 of the flange 85 includes a number of spikes 91 or blades 130 projecting therefrom. The spikes or blades are  
20 configured to penetrate the end plate of the adjacent vertebral bodies to help maintain the position of the implant in situ.

As shown in FIGS. 7 and 8, the endplates 83 include an arm 94 projecting from the flange 85, which is a component of a means for connecting the implant to a longitudinal member, such as rod 105. A rod bore 95 is defined adjacent the free  
25 end 94a of the arm 94, with a set screw bore 96 intersecting the rod bore 95 from the free end of the arm 94. A set screw 98 is provided which is engaged within the set screw bore 96 to clamp a rod passing therethrough.

The manner of using the replacement assembly 80 in this embodiment is shown in FIGS. 8 and 9. In particular, the endplates 83 are engaged in the appropriate

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vertebrae by way of spikes 91 or blades 130. Again, the plates are configured to define an angle 115 to correspond to the proper spinal anatomy at the particular vertebral level. A distraction plate 107 is mounted into each of the intact vertebrae by way of bone screw 108. The plate 107 includes a collar 109 integrally formed thereon through which a distraction rod 105 passes. The distraction rod also extends through each of the rod bores 95 in the arms 94 of the endplates 83. With the rod extending through each of the bores, the set screws 98 fix the endplates in position. Distraction of the adjacent vertebrae can be achieved by an appropriately formed instrument that can engage the collars 109 of each of the distraction plates 107 10 mounted into the respective vertebrae. A set screw (not shown) can be provided to fix the rod 105 within each collar 109.

Referring to FIGS. 7, 9 and 10, details of the manner in which the endplates are fixed to the threaded cylindrical body is described. In particular, the endplates 83, and particularly the cylinder 87 of the endplates, is provided with a means for fixing 15 in the form of a crimping channel 100 around the diameter of the cylinder. At opposite sides of the cylinder, a crimping notch 101 is provided in the channel 100. In essence, this crimping notch is a gap in the outer circumference of the channel 100. This crimping notch provides a gap which can be closed by an appropriate crimping tool gripping the entire circumference of the crimping channel 100. As the 20 crimping tool is tightened, the notches 101 close as the channel moves together in the direction of the arrows 102. It can be seen that this crimping aspect will replace the set screw 24 disclosed with the previous embodiment for fixing the endplates to the threaded cylindrical body.

While the invention has been illustrated and described in detail in the drawings 25 and foregoing description, the same is to be considered as illustrative and not restrictive in character, it being understood that only the preferred embodiments have been shown and described and that all changes and modifications that come within the spirit of the invention are desired to be protected.

What is claimed is:

1. A device for fixation of a vertebral replacement implant interposed in a space left by one or more removed vertebrae between adjacent intact vertebrae,  
5 comprising:
  - a replacement body with opposite ends sized to span the space between the intact vertebrae; and
  - 10 a pair of endplates attached to each of said opposite ends, said endplates having an end surface for contacting an intact vertebra when the implant is interposed in the space; and
  - 15 a plurality of blades integrally attached to each of said endplates, said blades projecting from said end surface for insertion in a corresponding one of the adjacent intact vertebra.
- 15 2. The device according to claim 1, wherein said blades are wedge-shaped.
3. The device according to claim 1, wherein said endplate defines a bore therethrough opening at said end surface.
- 20 4. The device according to claim 1, further comprising an end cap for closing said bore.
- 25 5. The device according to claim 4, wherein  
said replacement body includes a wall defining a hollow interior; and  
said hollow interior contains bone growth material disposed within said replacement body; and  
said end cap includes a porous body to allow vascularization between the existing intact vertebrae and said bone growth material.

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6. A device for fusion of the existing intact vertebrae through a vertebral replacement implant interposed in a space left by one or more removed vertebrae between adjacent intact vertebrae, comprising:

5 a replacement body with opposite ends sized to span the space between the intact vertebrae, said replacement body includes a cylindrical wall defining a hollow interior, said hollow interior contains bone growth material disposed within said replacement body; and

a pair of endplates attached to each of said opposite ends, each of said endplates having an end surface defining a bore through said endplate; and

10 an end cap for closing said bore, said end cap including a body formed of a porous material.

7. The device according to claim 6, wherein said porous material is formed to permit bone growth through said end cap.

15

8. The device according to claim 6, wherein said porous material includes interconnecting interstices throughout said body of said end cap.

20

9. The device according to claim 6, wherein said end cap is removable.

10. The device according to claim 6, wherein said end cap includes a positioning surface to align said end cap within said bore.

25

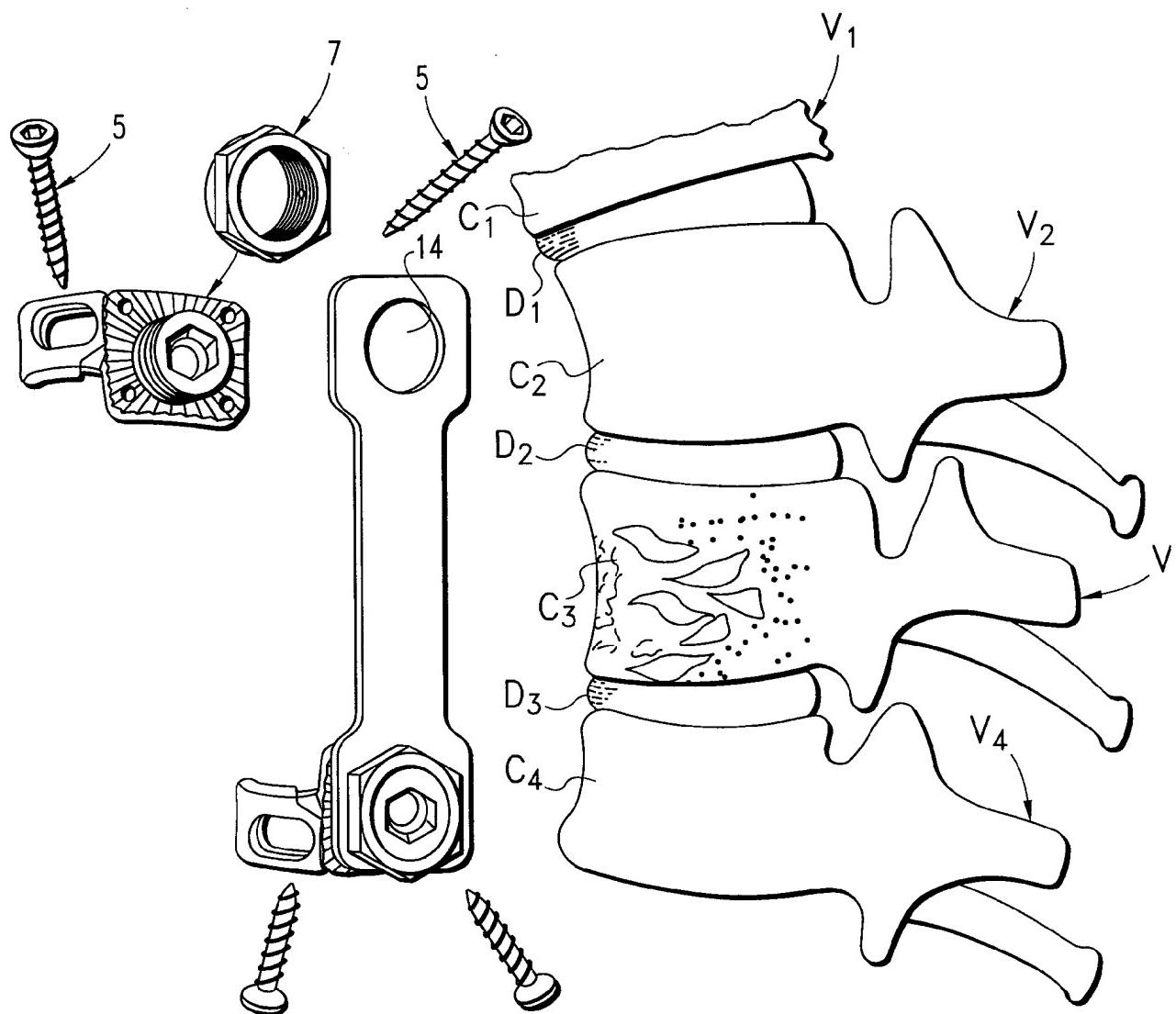
11. The device according to claim 6, wherein:

said end cap includes an anchor extending from said body and configured to project into said hollow interior, whereby  
said anchor is embedded in the bone growth material within said interior to secure said end cap to said end surface.

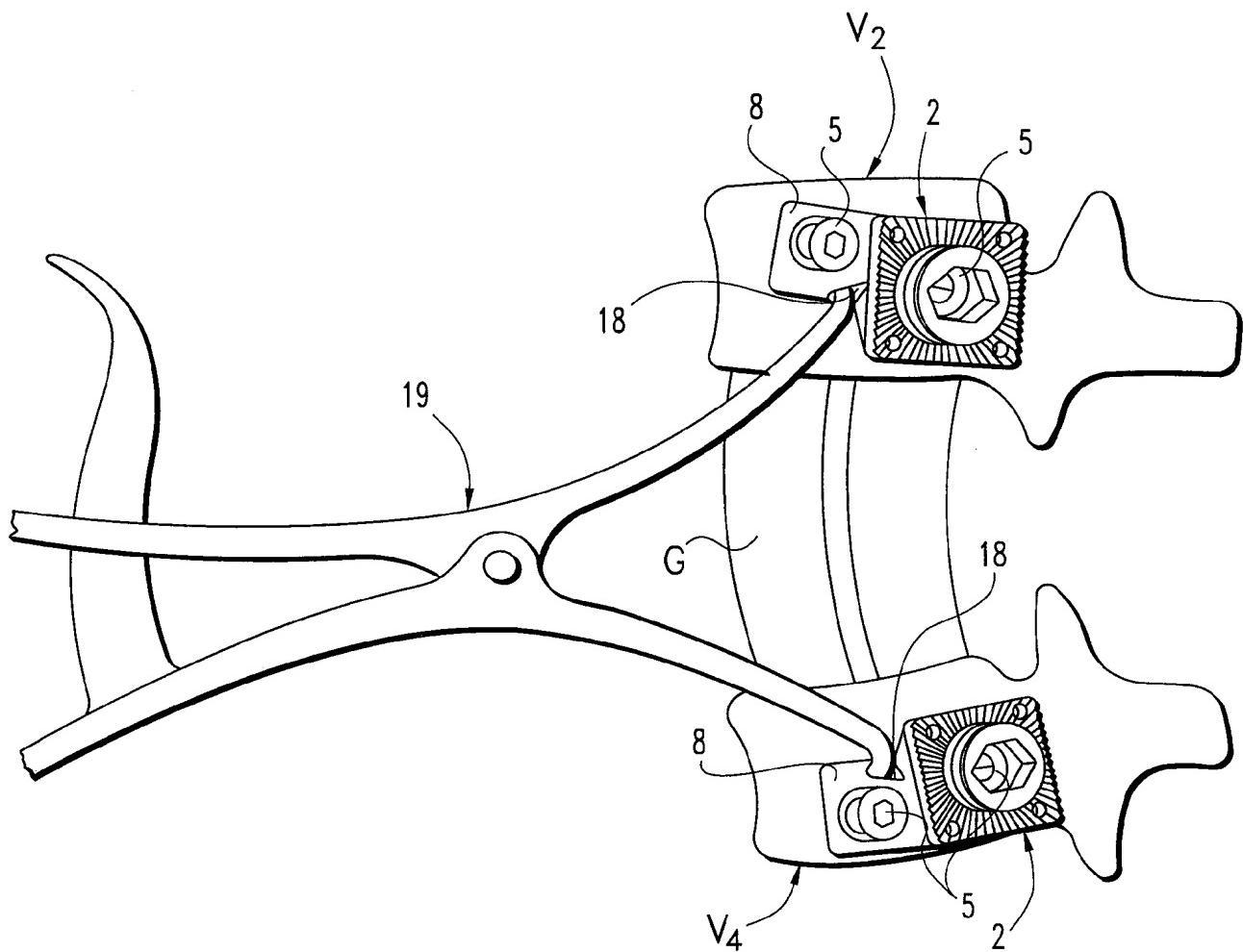
-23-

12. The device according to claim 6, wherein said porous body includes a porous tantalum material.

13. The device according to claim 6, wherein said porous body includes a  
5 porous metal.



**Fig. 1**  
(PRIOR ART)



**Fig. 2**  
(PRIOR ART)

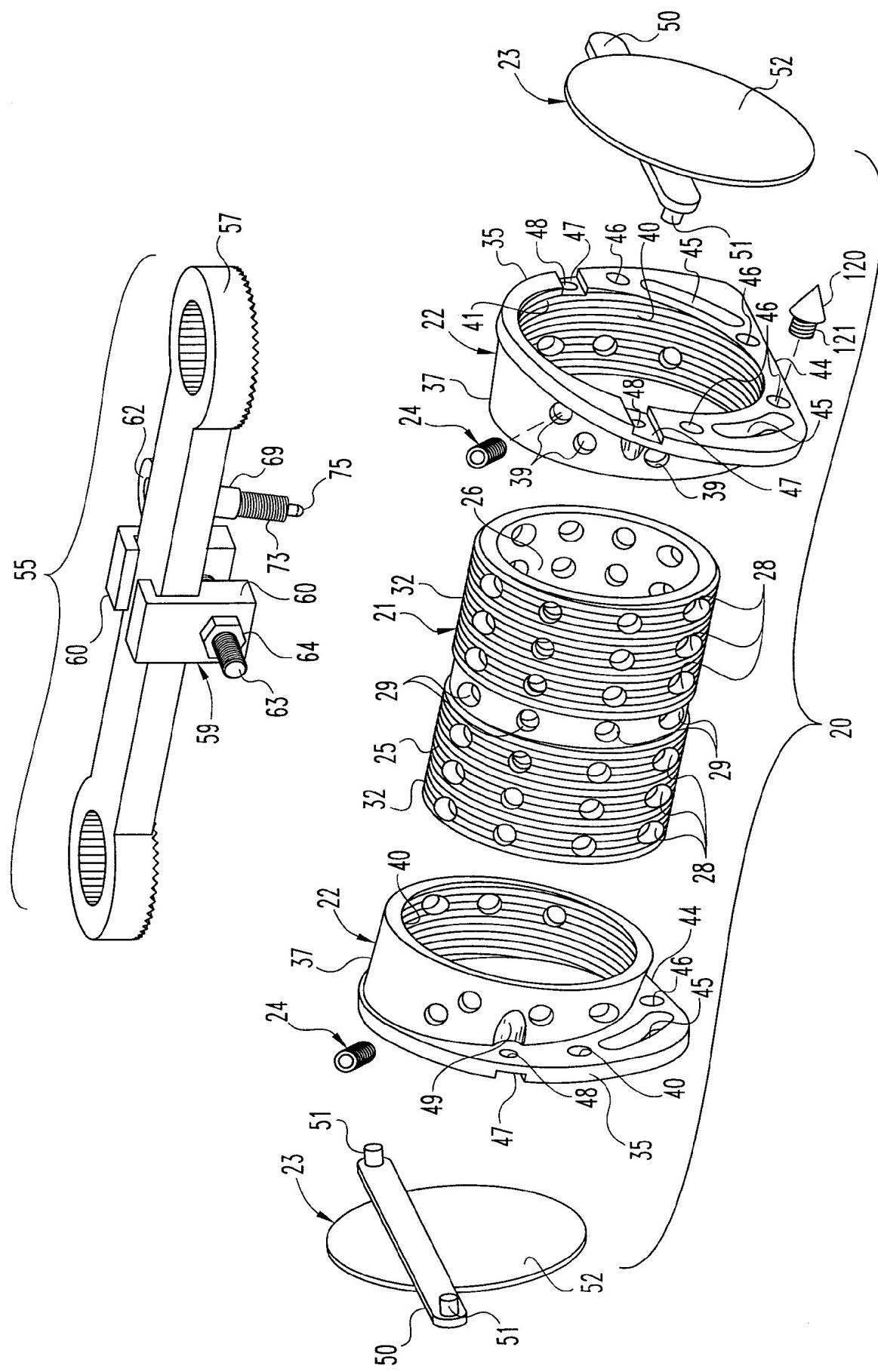
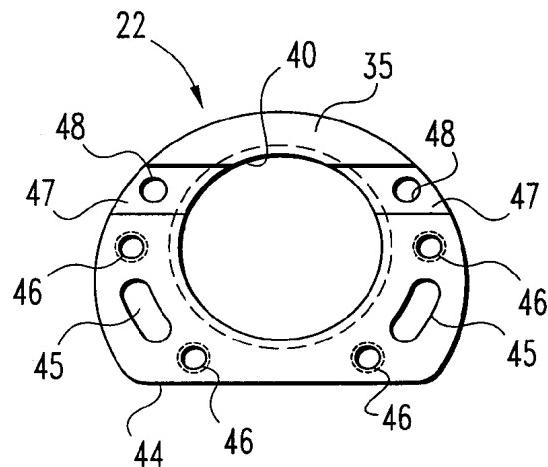
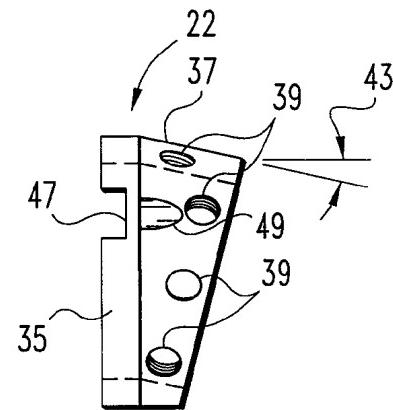
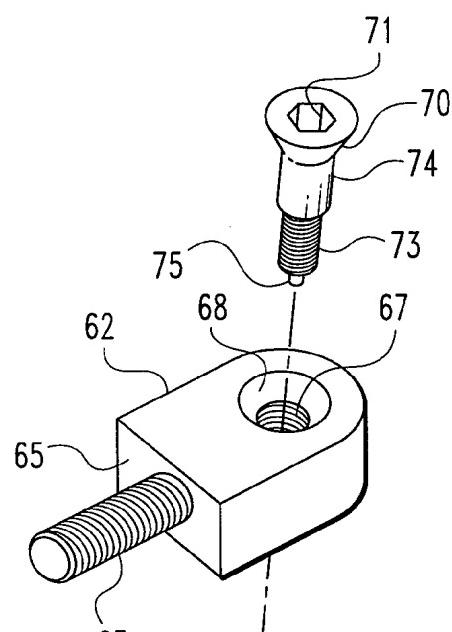
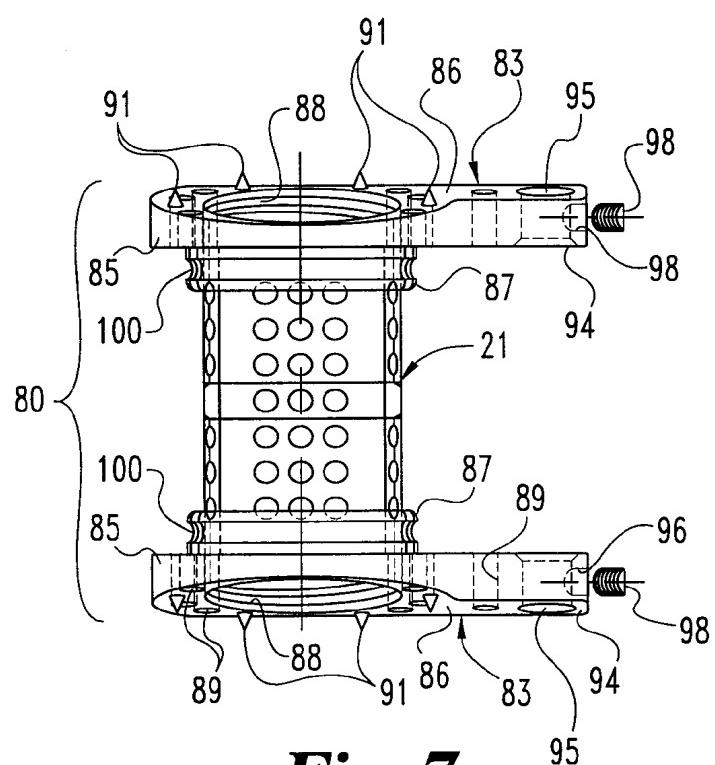
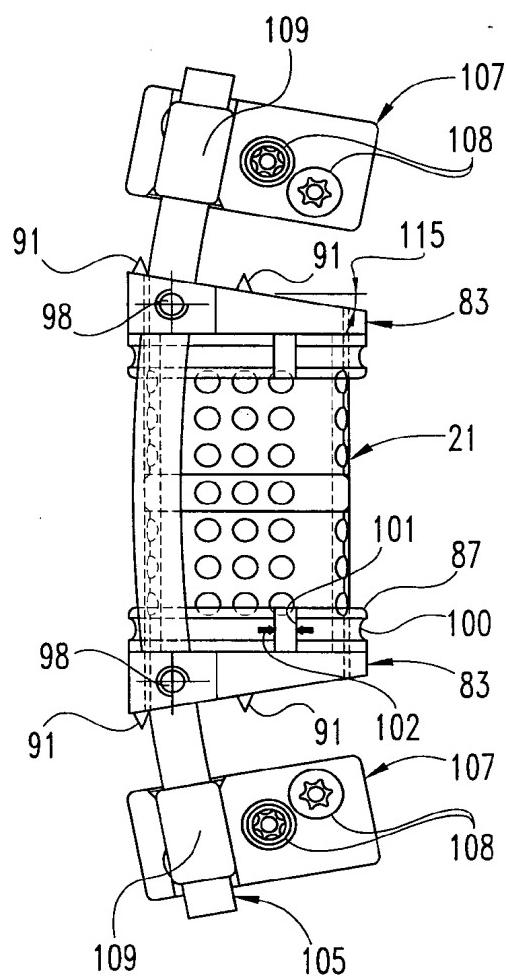
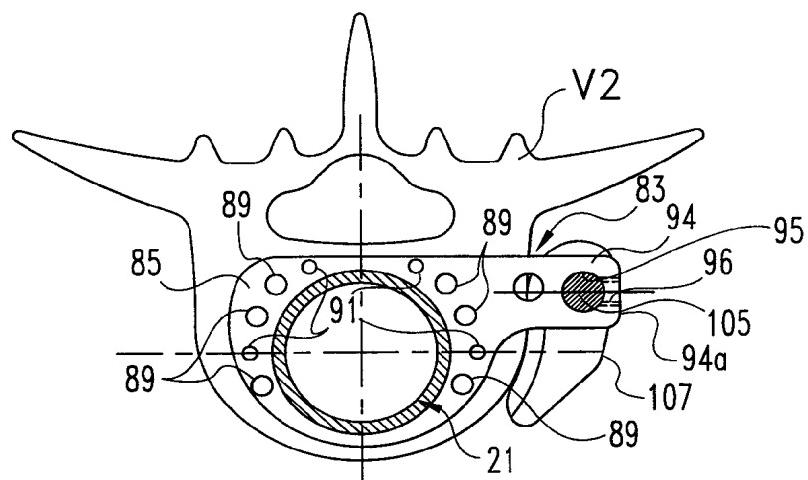
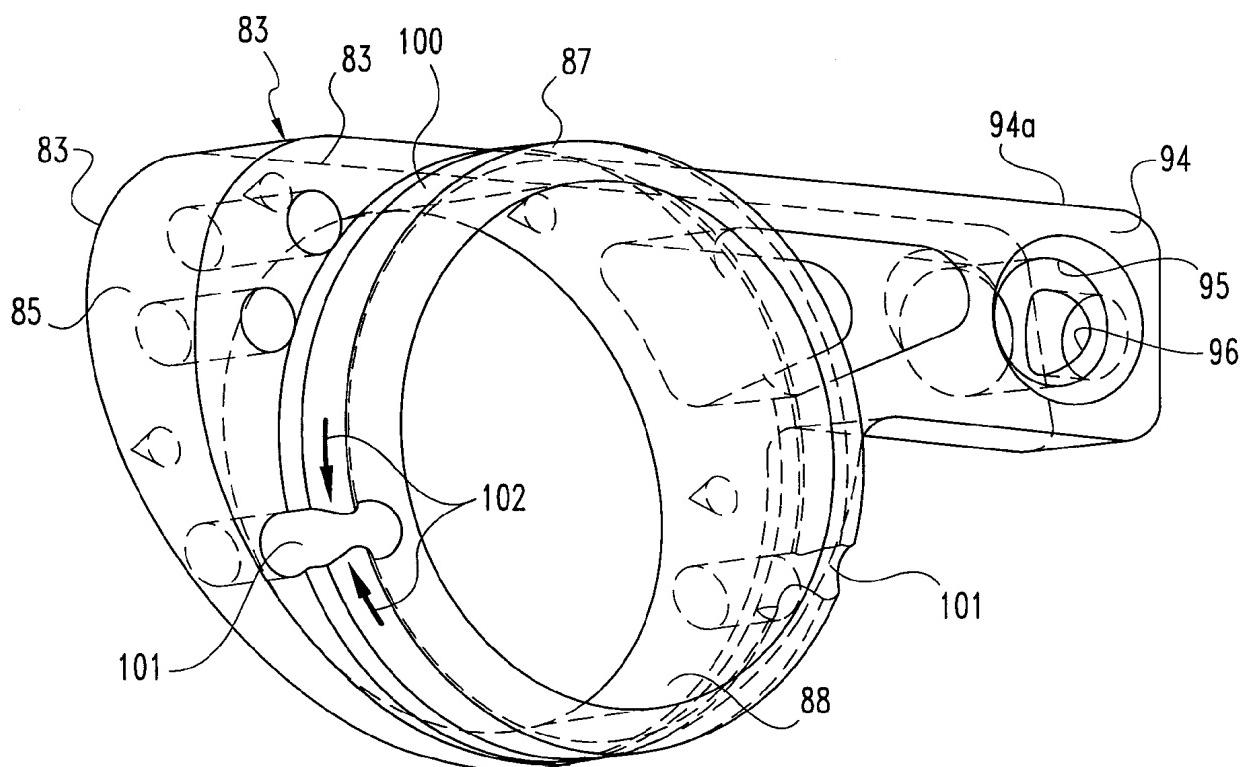


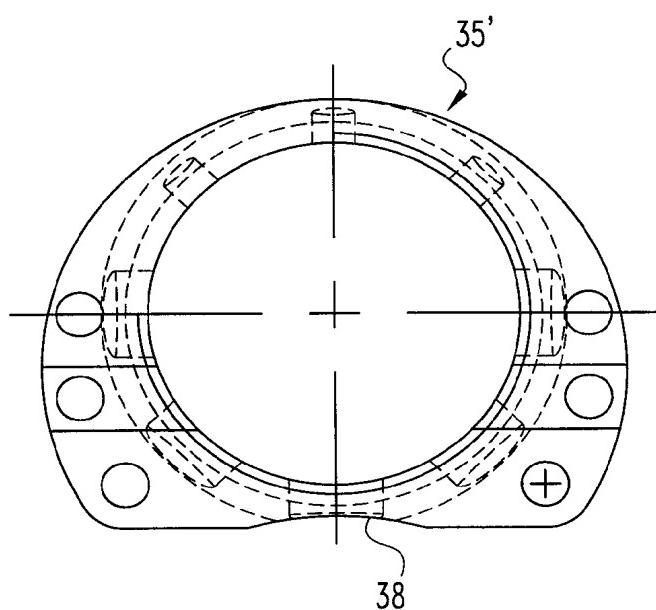
Fig. 3

**Fig. 4****Fig. 5****Fig. 6**

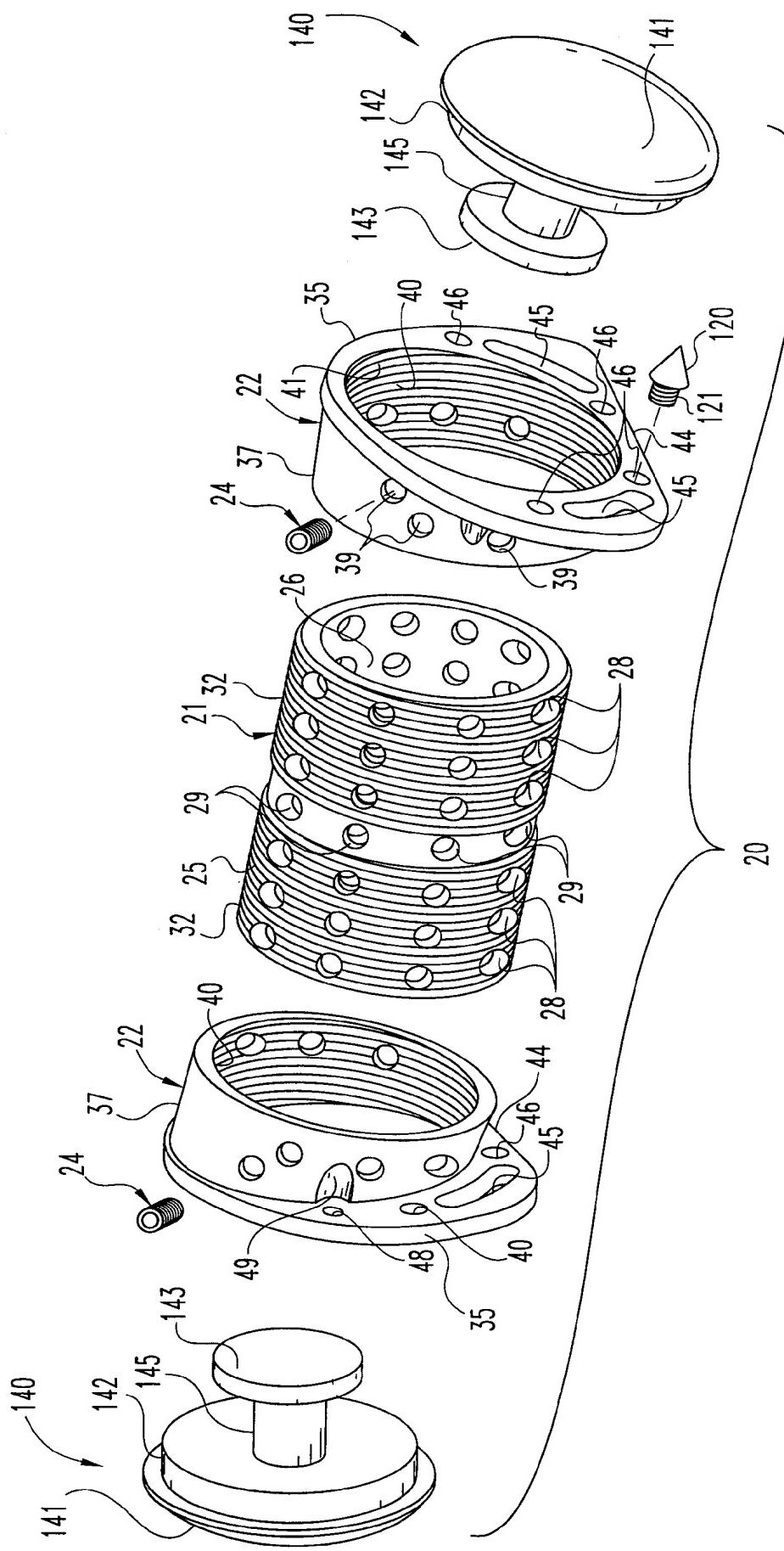
**Fig. 7****Fig. 9****Fig. 8**

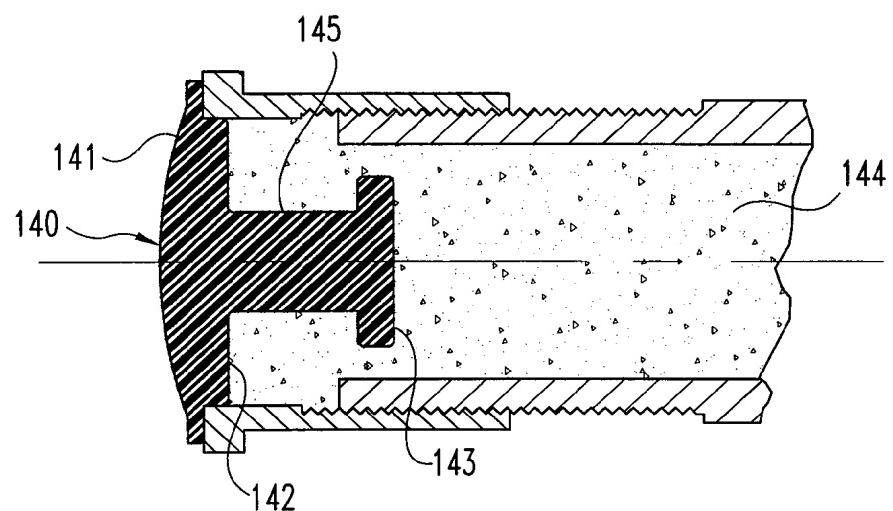


**Fig. 10**

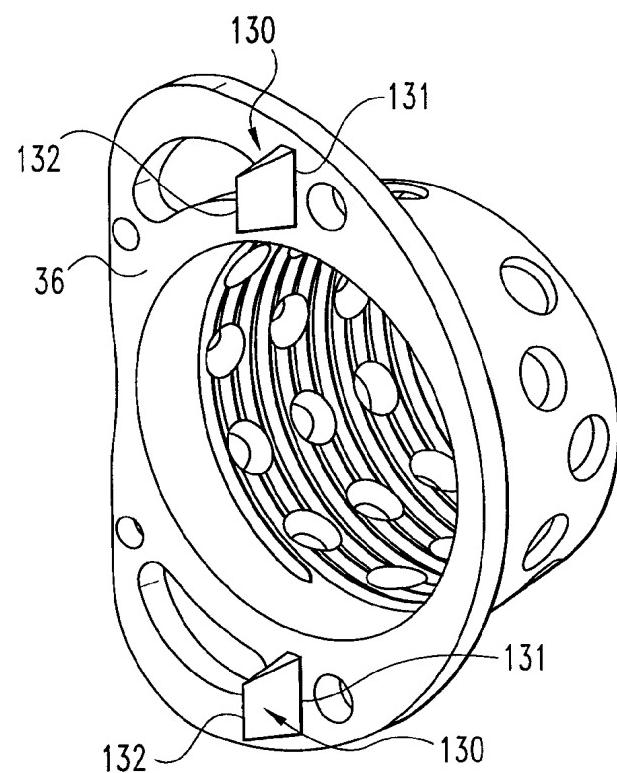


**Fig. 11**

**Fig. 12**



**Fig. 13**



**Fig. 14**

# INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 99/09271

**A. CLASSIFICATION OF SUBJECT MATTER**

IPC 6 A61F2/44

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 96 17564 A (SOFAMOR DANEK GROUP INC) 13 June 1996 (1996-06-13) cited in the application page 11, line 34 -page 12, line 6 page 12, line 26 - line 33 claims 1,8,18; figures ---	1
A	page 11, line 34 -page 12, line 6 page 12, line 26 - line 33 claims 1,8,18; figures ---	3-10
Y	DE 195 09 317 A (ULRICH HEINRICH) 19 September 1996 (1996-09-19)	1
A	column 5, line 30 - line 42; claims 9-12; figures ---	2
A	EP 0 567 424 A (APARICI MARIN JOSE J ;BARBERA ALACREU JOSE VICENTE (ES); BILBAO OR) 27 October 1993 (1993-10-27) abstract; figures ---	1,3 -/-



Further documents are listed in the continuation of box C.



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Date of the actual completion of the international search

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## INTERNATIONAL SEARCH REPORT

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## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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A	US 5 458 641 A (RAMIREZ JIMENEZ JUAN J) 17 October 1995 (1995-10-17) column 4, line 42 - line 52; claim 5 ---	1,6
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**INTERNATIONAL SEARCH REPORT**

Information on patent family members

International Application No

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US 5458641	A 17-10-1995	NONE			
WO 9520370	A 03-08-1995	US 5443515	A 22-08-1995	AU 1604295	A 15-08-1995

(51) Internationale Patentklassifikation <sup>6</sup> : <b>A61F 2/44, A61L 27/00</b>	A1	(11) Internationale Veröffentlichungsnummer: <b>WO 98/09586</b>  (43) Internationales Veröffentlichungsdatum: <b>12. März 1998 (12.03.98)</b>
(21) Internationales Aktenzeichen: <b>PCT/CH96/00303</b>	(81) Bestimmungsstaaten: CA, JP, US, europäisches Patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).	
(22) Internationales Anmeldedatum: <b>4. September 1996 (04.09.96)</b>	Veröffentlicht <i>Mit internationalem Recherchenbericht.</i>	
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<p><b>(54) Title:</b> INTERVERTEBRAL IMPLANT</p> <p><b>(54) Bezeichnung:</b> ZWISCHENWIRBEL-IMPLANTAT</p> <p><b>(57) Abstract</b></p> <p>A hollow cylindrical intervertebral implant with a longitudinal axis (3), a covering surface (1) and a base surface (2), made essentially of a ceramic material presenting a maximum porosity of 30 vol. % and which pores are filled with air. The inventive implant is distinguished by the fact that it compensates the distance (corresponding to intervertebral disk height) - after successful primary fusion - between both vertebral bodies during the absorption process - upon adequate fusion - and is resorbed by said bodies after a certain amount of time.</p> <p><b>(57) Zusammenfassung</b></p> <p>Das hohlzylinderförmige Zwischenwirbel-Implantat mit der Längsachse (3), der Deckfläche (1) und der Grundfläche (2) besteht im wesentlichen aus einem keramischen Werkstoff, der eine Porosität von höchstens 30 Vol.-% aufweist und dessen Poren mit Luft gefüllt sind. Das erfindungsgemäße Implantat zeichnet sich dadurch aus, dass es - nach erfolgter Primärfusion - die Distanz (entsprechend der Bandscheibenhöhe) zwischen den beiden Wirbelkörpern während des Resorptionsprozesses - bei gleichzeitig adäquater Fusion - ausgleicht und nach einer bestimmten Zeit vom Körper resorbiert wird.</p>		

***LEDIGLICH ZUR INFORMATION***

Codes zur Identifizierung von PCT-Vertragsstaaten auf den Kopfbögen der Schriften, die internationale Anmeldungen gemäss dem PCT veröffentlichen.

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**Zwischenwirbel-Implantat**

Die Erfindung betrifft ein Zwischenwirbel-Implantat gemäss dem Oberbegriff des Patentanspruchs 1.

Solche Zwischenwirbel-Implantate werden bei der Fusion von Wirbelkörpern - nach der Entfernung der dazwischenliegenden Bandscheibe - eingesetzt, insbesondere im Bereich der lumbalen Wirbelsäule. Pro Zwischenwirbelraum werden ein bis zwei Implantate verwendet.

Aus der EP-B 346.269 FUHRMANN ET AL. ist bereits ein Zwischenwirbelimplantat bekannt, bei dem die nach aussen weisenden Stirn- und Seiten-Oberflächen des Implantats aus Hydroxyl-Apatit oder keramischem HIP-Material beschichtet sind. Nachteilig bei diesem bekannten Implantat ist der Umstand, dass der Grundkörper des Implantats aus üblichen nicht-keramischen und damit auch nicht-resorbierbaren Materialien besteht.

Aus der US-A-5 306 303 LYNCH ist bereits ein Zwischenwirbel-Implantat bekannt, welches vollständig aus einem porösen keramischen Material besteht. Nachteilig bei diesem bekannten Implantat ist jedoch einerseits die geringe Druckstabilität, die

sich aus der relativ hohen Porosität ergibt und anderseits, dass sich das Implantat nicht mit Knochenspänen füllen lässt, um eine schnellere Knochen-Einbettung zu erzielen.

Aus der EP 505 634 OKA et al. ist schliesslich ein weiteres Zwischenwirbelimplantat bekannt, welches aus einem porösen Keramik-Grundkörper mit in den Poren eingelagertem Hydrogel besteht. Auch bei diesem bekannten Implantat ist, wegen seiner mit Hydrogel gefüllten Poren, die Druckstabilität ungenügend.

Hier will die Erfindung Abhilfe schaffen. Der Erfindung liegt die Aufgabe zugrunde, ein Zwischenwirbel-Implantat zu schaffen, welches den verschiedenen Krafteinwirkungen an der Wirbelsäule standhalten kann und eine genügend grosse Auflage an den Endplatten aufweist, um ein Einsinken derselben zu verhindern. Es soll zudem eine möglichst rasche Fusion der beiden Wirbelkörper und eine rasche Inkorporation des Implantats ermöglichen unter Berücksichtigung der Höhe, welche die Bandscheibe vor deren Entfernung einnahm. In einem nächsten Schritt soll sich das Implantat vollständig (oder annähernd vollständig) durch körpereigenen Knochen ersetzen können.

Zur Lösung dieses Problems ist das eingangs genannte Implantat durch die Merkmale des kennzeichnenden Teils des unabhängigen Anspruchs 1 weitergebildet.

Damit ist der Vorteil erzielbar, dass das erfindungsgemässse Implantat - nach der erfolgten Primärfusion - die Distanz (entsprechend der Bandscheibenhöhe) zwischen den beiden Wirbelkörpern während des Resorptionsprozesses - bei gleichzeitig adäquater Fusion - ausgleicht und dass das Implantat nach einer bestimmten Zeit, wegen der auftretenden Resorption, im Körper nicht mehr nachweisbar ist.

Ein weiterer wesentlicher Vorteil ergibt sich auch aus der Röntgentransparenz des Implantats, welche störende Effekte bei der Beurteilung der umliegenden knöchernen Strukturen vermeidet..

Das Zwischenwirbelimplantat kann entweder als prismatischer oder zylindrischer Körper ausgebildet sein. Gemäss einer bevorzugten Weiterbildung der Erfindung beträgt die Porosität des keramischen Werkstoffs höchstens 9 Vol.-%, vorzugsweise höchstens 5 Vol.-%. Dank der verringerten Porosität des Implantats ergibt sich eine hohe Druckfestigkeit, was vor allem im lumbalen Bereich der Wirbelsäule eine Grundvoraussetzung bildet. Eine möglichst grosse druckstabile Kontaktfläche von Endplatte zu Implantat ist hier wichtig. Deshalb sollte die Wandstärke des ringförmigen Zwischenwirbel-Implantats mindestens 4 mm, vorzugsweise mindestens 6 mm betragen, um einem Einsinken des Implantats in die Endplatten vorzubeugen.

Bei einer weiteren bevorzugten Ausführungsform der Erfindung beträgt die Dichte des keramischen Werstoffs mehr als 2,8, vorzugsweise mehr als 3,1, was die Druckfestigkeit des Implantats weiter verbessert.

Vorzugsweise ist das Implantat als hohler Kreiszylinder ausgebildet, um das Einbringen von körpereigenen Knochenspänen oder ähnlichen biokompatiblen Materialien zu ermöglichen und somit einer raschen Fusion des Implantats Vorschub zu leisten.

Gemäss einer weiteren bevorzugten Ausführungsform der Erfindung ist die Deckfläche und/oder die Grundfläche des Implantats nicht planar ausgebildet, sondern weist quer zur Zylinderachse des Implantats verlaufenden Rillen und/oder Erhöhungen auf. Diese dreidimensionale Strukturierung der Deck- und Grundfläche ermöglicht direkt nach dem Einführung des Implantats in den Zwischenwirbelraum eine Primärverankerung, womit die Lagestabilität des Implantats, bzw. die Rotationsstabilität der benachbarten Wirbelkörper erhöht wird. Die dreidimensionale Strukturierung ist vorzugsweise in Form von "Wellen" (Erhöhungen, bzw. Versteifungen mit ausgeprägten Radien) in Längs- und Querrichtung ausgebildet.

Je nach Anwendungsbereich des Implantats ist die Deckfläche und/oder die Grundflächen parallel oder keilförmig zueinander zulaufend angeordnet, um in jedem Bereich der Wirbelsäule die Kurvenbildung adäquat nachformen zu können (Lordose, Kyphose).

Das Implantat besitzt vorzugsweise eine nach aussen gewölbte konvexe Deckfläche und/oder Grundfläche, welche der konkaven Formgebung der natürlichen Wirbelkörper-Endplatten angeglichen ist, um eine bessere Kontaktzone zwischen Implantat und Endplatten zu erreichen.

Vorzugsweise weist der Mantel des Zwischenwirbel-Implantats eine oder mehrere Perforationen auf, welche primär der Aufnahme eines Instrumentes zur Manipulation des Implantats dienen. Die Perforationen können sowohl an der anterioren Seite des Implantats, als auch in der lateralen Zone des Implantats angebracht werden. Im weiteren dienen die Perforationen in der Mantelfläche zur Förderung der primären knöchernen Durchbauung des Implantats.

Die Lagestabilität des Implantats kann noch dadurch verbessert werden, dass der Mantel des Zwischenwirbel-Implantat mit einer feinen dreidimensionalen Strukturierung versehen wird, welche das Anwachsen des Knochens in einer frühen Phase fördert. Diese Feinstrukturierung ist vorzugsweise 0,5 - 1,0 mm tief bei einer Rillenbreite von 0,5 - 1,0 mm. Die Anordnung der Strukturierung kann über die gesamte Mantelfläche erfolgen.

Für das erfindungsgemäße Implantat eignen sich die üblichen in der Medizin bereits erprobten keramischen Materialien mit der erfindungsgemäss definierten Porosität, wobei insbesondere polykristalline Keramiken bevorzugt werden, bei welchen der Fremdphasenanteil kleiner als 3 vorzugsweise kleiner als 2

Gew.-% ist. Die Druckfestigkeit des keramischen Werkstoffs beträgt zweckmässigerweise 400 - 600 MPa, vorzugsweise 450 - 550 MPa.

Die Erfindung und Weiterbildungen der Erfindung werden im folgenden anhand der teilweise schematischen Darstellungen eines Ausführungsbeispiels noch näher erläutert.

Die einzige Figur zeigt:

Eine perspektivische Darstellung des erfindungsgemässen Implantats.

Das in der einzigen Figur dargestellte Zwischenwirbel-Implantat besteht im wesentlichen aus einem Hohlzylinder mit Innenraum 8, Längsachse 3, Deckfläche 1 und Grundfläche 2. Das Zwischenwirbel-Implantat besteht im wesentlichen aus einem polykristallinen, keramischen Werkstoff. Der keramische Werkstoff weist eine Porosität von 5 Vol.-% auf, wobei die Poren mit Luft gefüllt sind. Die Porenweite ist kleiner als 100 µm, vorzugsweise kleiner als 50 µm.

Der Fremdphasenanteil des keramischen Materials beträgt 1,5 Gew.-%. Die Druckfestigkeit des keramischen Werkstoffs beträgt 500 MPa.

Die Deck- und Grundflächen 1,2 sind für den Knochenkontakt zu den Deckplatten zweier Wirbelkörper bestimmt und entsprechend ausgebildet. Die Wandstärke des Zwischenwirbel-Implantats beträgt 7 mm und die Dichte des keramischen Werkstoffs beträgt 3,2. Die Deckfläche 1 und die Grundfläche 2 sind nicht planar ausgebildet, sondern sind mit einer Anzahl quer (d.h. radial) zur Längsachse 3 verlaufender Rillen 4 und Erhöhungen 5 versehen.

Die Deckfläche 1 und die Grundfläche 2 sind zueinander keilförmig zulaufend angeordnet und sind leicht nach aussen konvex gewölbt.

Im Mantel 6 des Zwischenwirbel-Implantats ist anterior eine Perforation 7 vorgesehen, welche der Aufnahme eines Manipulations-Instrumentes dient. Der Mantel ist ferner mit einer dreidimensionalen Strukturierung 9 versehen, welche eine Tiefe von 0,75 mm aufweist.

Nachstehend wird nun die klinische Anwendung des erfindungsgemässen Zwischenwirbelimplantats im Detail beschrieben.

Das in der einzigen Figur gezeigte Implantat wird mit Knochenspänen (bone graft oder Knochenersatzmaterial), eventuell unter Komprimierung derselben, gefüllt, mit einem geeigneten in die Perforation 7 eingeführten Instrument gefasst und unter

Zuhilfenahme eines Distraktionsinstrumentes in den ausgeräumten Zwischenwirbelraum eingeführt.

Patentansprüche

1. Zwischenwirbel-Implantat prismatischer oder zylindrischer Gestalt mit der Längsachse (3), dessen Deckfläche (1) und Grundfläche (2) für den Knochenkontakt zu den Deckplatten zweier Wirbelkörper bestimmt sind, wobei das Zwischenwirbel-Implantat im wesentlichen aus einem keramischen Werkstoff besteht,  
**dadurch gekennzeichnet, dass**
  - A) der keramische Werkstoff eine Porosität von höchstens 30 Vol.-% aufweist und
  - B) die Poren des keramischen Werkstoffs mit Luft gefüllt sind.
2. Implantat nach Anspruch 1, dadurch gekennzeichnet, dass die Porosität des keramischen Werstoffs höchstens 9 Vol.-%, vorzugsweise höchstens 5 Vol.-% beträgt.
3. Implantat nach Anspruch 1 oder 2, dadurch gekennzeichnet, dass die Wandstärke des Zwischenwirbel-Implantats mindestens 4 mm, vorzugsweise mindestens 6 mm beträgt.
4. Implantat nach einem der Ansprüche 1 bis 3, dadurch gekennzeichnet, dass die Dichte des keramischen Werstoffs grösser als 2,8, vorzugsweise grösser als 3,1 ist.
5. Implantat nach einem der Ansprüche 1 bis 4, dadurch gekennzeichnet, dass das Zwischenwirbel-Implantat als hohler Kreiszylinder mit der Längsachse (3) ausgebildet ist.

6. Implantat nach einem der Ansprüche 1 bis 5, dadurch gekennzeichnet, dass die Deckfläche (1) und/oder die Grundfläche (2) nicht planar ausgebildet ist und vorzugsweise mit quer zur Längsachse (3) verlaufenden Rillen (4) und/oder Erhöhungen (5) versehen ist.
7. Implantat nach einem der Ansprüche 1 bis 6, dadurch gekennzeichnet, dass die Deckfläche (1) und die Grundfläche (2) parallel zueinander angeordnet sind.
8. Implantat nach einem der Ansprüche 1 bis 6, dadurch gekennzeichnet, dass die Deckfläche (1) und die Grundfläche (2) keilförmig zueinander zulaufend angeordnet sind.
9. Implantat nach einem der Ansprüche 1 bis 8, dadurch gekennzeichnet, dass die Deckfläche (1) und/oder die Grundfläche (2) nach aussen konvex gewölbt ist.
10. Implantat nach einem der Ansprüche 1 bis 9, dadurch gekennzeichnet, dass der Mantel (6) des Zwischenwirbel-Implantats mit einer oder mehreren Perforationen (7) versehen ist.

11. Implantat nach einem der Ansprüche 1 bis 10, dadurch gekennzeichnet, dass der Mantel (6) des Zwischenwirbel-Implantat mit einer dreidimensionalen Strukturierung (9) versehen ist, vorzugsweise mit einer Tiefe der Strukturierung von 0,5 - 1,0 mm.

12. Implantat nach einem der Ansprüche 1 bis 11, dadurch gekennzeichnet, dass das keramische Material polykristallin ist.

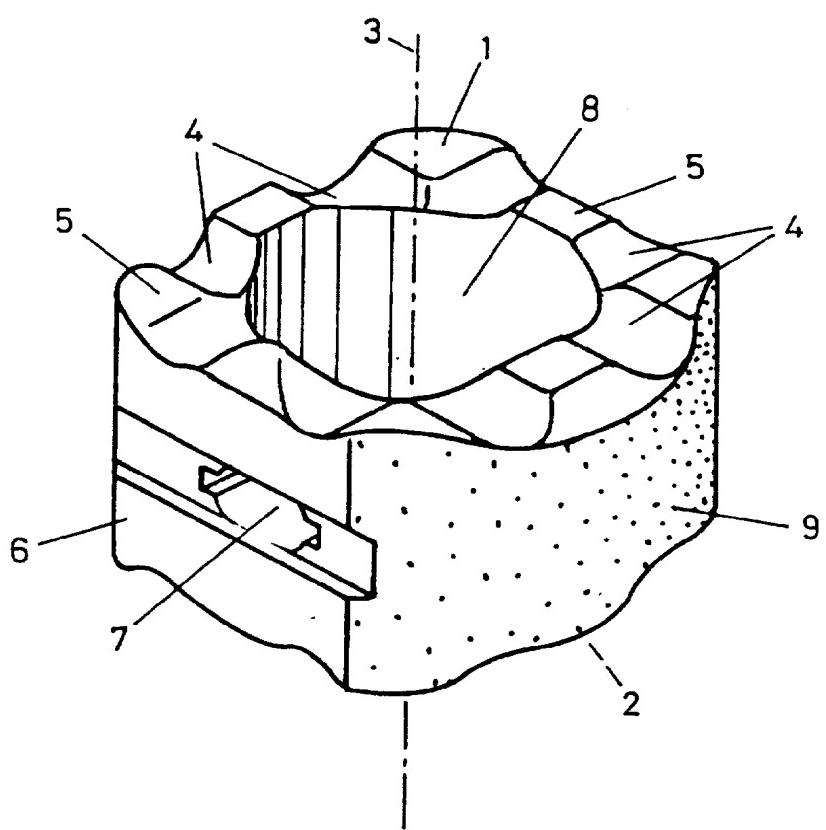
13. Implantat nach einem der Ansprüche 1 bis 12, dadurch gekennzeichnet, dass das keramische Material einen Fremdphasenanteil von kleiner als 3 vorzugsweise kleiner als 2 Gew.-% aufweist.

14. Implantat nach einem der Ansprüche 1 bis 13, dadurch gekennzeichnet, dass die Druckfestigkeit des keramischen Werkstoffs 400 - 600 MPa, vorzugsweise 450 - 550 MPa beträgt.

15. Implantat nach einem der Ansprüche 1 bis 14, dadurch gekennzeichnet, dass die Porenweite kleiner als 100  $\mu\text{m}$ , vorzugsweise kleiner als 50  $\mu\text{m}$  ist.

16. Implantat nach einem der Ansprüche 1 bis 15, dadurch gekennzeichnet, dass der keramische Werkstoff röntgentransparent ist.

1/1



# INTERNATIONAL SEARCH REPORT

In International Application No  
PCT/CH 96/00303

**A. CLASSIFICATION OF SUBJECT MATTER**  
IPC 6 A61F2/44 A61L27/00

According to International Patent Classification (IPC) or to both national classification and IPC

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IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 493 698 A (HÄRLE) 8 July 1992 see the whole document ---	1,8,10, 15
A	WO 88 03417 A (MATERIAL CONSULTANTS OY) 19 May 1988 see page 24, line 9 see page 32, line 11 - line 20 see abstract; figures 6,7 ---	1,7,16
A	US 4 683 161 A (RICE) 28 July 1987 see column 1, line 47 - line 54 see column 9, line 54 - line 56 ---	1 -/-

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Date of the actual completion of the international search

Date of mailing of the international search report

12 May 1997

20.05.97

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## INTERNATIONAL SEARCH REPORT

In	national Application No PCT/CH 96/00303
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## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 505 634 A (KYOCERA CORPORATION) 30 September 1992 cited in the application see page 5, line 25; figures 2-4 see abstract; claim 6 ----	1,7
A	DE 44 23 826 A (ASAHI KOGAKU KOGYO) 12 January 1995 see claims 1,5; figure 2 ----	1,9
A	US 5 306 309 A (WAGNER) 26 April 1994 see column 7, line 9 - line 23; claim 13; figures 3-9 ----	1,6-8,15
A	FR 2 703 580 A (ROBERT) 14 October 1994 see abstract; figure 1 ----	6,8,16
A	US 5 306 303 A (LYNCH) 26 April 1994 cited in the application -----	

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Information on patent family members

International Application No

PCT/CH 96/00303

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FR 2703580 A	14-10-94	NONE	
US 5306303 A	26-04-94	NONE	

# INTERNATIONALER RECHERCHENBERICHT

Internationales Aktenzeichen  
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**A. KLASIFIZIERUNG DES ANMELDUNGSGEGENSTANDES**  
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**C. ALS WESENTLICH ANGEGEHENE UNTERLAGEN**

Kategorie*	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
A	EP 0 493 698 A (HÄRLE) 8.Juli 1992 siehe das ganze Dokument ---	1,8,10, 15
A	WO 88 03417 A (MATERIAL CONSULTANTS OY) 19.Mai 1988 siehe Seite 24, Zeile 9 siehe Seite 32, Zeile 11 - Zeile 20 siehe Zusammenfassung; Abbildungen 6,7 ---	1,7,16
A	US 4 683 161 A (RICE) 28.Juli 1987 siehe Spalte 1, Zeile 47 - Zeile 54 siehe Spalte 9, Zeile 54 - Zeile 56 --- -/-	1



Weitere Veröffentlichungen sind der Fortsetzung von Feld C zu entnehmen



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# INTERNATIONALER RECHERCHENBERICHT

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## C.(Fortsetzung) ALS WESENTLICH ANGESEHENE UNTERLAGEN

Kategorie	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
A	EP 0 505 634 A (KYOCERA CORPORATION) 30.September 1992 in der Anmeldung erwähnt siehe Seite 5, Zeile 25; Abbildungen 2-4 siehe Zusammenfassung; Anspruch 6 ---	1,7
A	DE 44 23 826 A (ASAHI KOGAKU KOGYO) 12.Januar 1995 siehe Ansprüche 1,5; Abbildung 2 ---	1,9
A	US 5 306 309 A (WAGNER) 26.April 1994 siehe Spalte 7, Zeile 9 - Zeile 23; Anspruch 13; Abbildungen 3-9 ---	1,6-8,15
A	FR 2 703 580 A (ROBERT) 14.Oktober 1994 siehe Zusammenfassung; Abbildung 1 ---	6,8,16
A	US 5 306 303 A (LYNCH) 26.April 1994 in der Anmeldung erwähnt -----	

**INTERNATIONALER RECHERCHENBERICHT**

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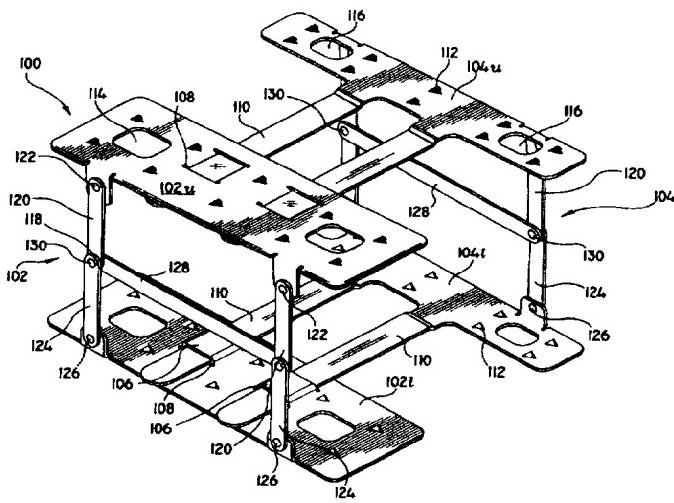
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Im Recherchenbericht angeführtes Patentdokument	Datum der Veröffentlichung	Mitglied(er) der Patentfamilie	Datum der Veröffentlichung
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EP 505634 A	30-09-92	JP 4303444 A US 5458643 A US 5314478 A	27-10-92 17-10-95 24-05-94
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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<b>(51) International Patent Classification</b> <sup>6</sup> : <b>A61F 2/44</b>		<b>A1</b>	<b>(11) International Publication Number:</b> <b>WO 98/14142</b>
<b>(21) International Application Number:</b> PCT/US97/17383		<b>(43) International Publication Date:</b> 9 April 1998 (09.04.98)	
<b>(22) International Filing Date:</b> 26 September 1997 (26.09.97)		<b>(81) Designated States:</b> AU, CA, JP, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).	
<b>(30) Priority Data:</b> 08/725,666 1 October 1996 (01.10.96) US		<b>Published</b> <i>With international search report.</i>	
<b>(71) Applicant:</b> SURGICAL DYNAMICS, INC. [US/US]; 111 Glover Avenue, Norwalk, CT 06856 (US).			
<b>(72) Inventors:</b> LARSEN, Scott, W.; 18 Sugar Hill Road, Newtown, CT 06470 (US). SHIKHMAN, Oleg; 80 Camp Field Drive, Fairfield, CT 06432 (US).			
<b>(74) Agent:</b> GERSHON, Neil, D.; United States Surgical Corporation, 150 Glover Avenue, Norwalk, CT 06856 (US).			

(54) Title: SPINAL FUSION IMPLANT AND METHOD OF INSERTION THEREOF



**(57) Abstract**

A spinal fusion implant includes lower and upper plate members (1021, 1041, 102u, 104u) dimensioned for at least partial insertion within the intervertebral space defined between adjacent vertebrae. The lower and upper plate members (1021, 1041, 102u, 104u) have contacting surfaces (112) for engaging respective vertebral end faces of the adjacent vertebrae. A linkage mechanism (118) including at least one link member operatively connects the lower and upper plate members (1021, 1041, 102u, 104u). The linkage mechanism (118) is actuatable to cause relative movement of the lower and upper plate members (1021, 1041, 102u, 104u), wherein upon actuation, the contacting surfaces of the lower and upper plate members engage the vertebral end faces with the lower and upper plate members (1021, 1041, 102u, 104u) supporting the adjacent vertebrae in spaced relation during healing.

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5

**SPINAL FUSION IMPLANT  
AND METHOD OF INSERTION THEREOF**

**BACKGROUND**

1. **Technical Field**

The present disclosure relates generally to a surgical apparatus for fusing adjacent bone structures, and, more particularly, to an apparatus and method for fusing adjacent vertebrae.

2. **Background of the Related Art**

The fusion of adjacent bone structures is commonly performed to provide for long-term replacement to compensate for degenerative or deteriorated disorders in bone. For example, an intervertebral disc which is a ligamentous cushion disposed between adjacent vertebrae, may undergo deterioration as a result of injury, disease, tumor or other disorders. The disc shrinks or flattens leading to mechanical instability and painful disc translocations.

Conventional procedures for disc surgery include partial or total excision of the injured disc portion, e.g., discectomy, and replacement of the excised disc with biologically acceptable plugs or bone wedges. The plugs are driven between adjacent vertebrae to maintain normal intervertebral spacing and to achieve, over a period of time, bony fusion with the plug and opposed vertebrae. For example, U.S. Patent No. 4,887,020 to Vich discloses a cylindrical bone plug having a thread on its exterior, which is screwed into a correspondingly dimensioned cylindrical bore drilled in the intervertebral space.

Other devices and methods for intervertebral fusion are disclosed in U.S. Patent Nos. 4,863,477 to Monson; 4,874,389 to Downey; 4,932,969 to Fray et al;

5,306,307 to Senter et al; 5,306,308 to Gross et al.; and 5,401,269 to Buttner-Janz et al. The Monson '477 device discloses a synthetic intervertebral disc prosthesis molded in the same shape and general dimensions as a natural disc. The prosthesis includes two halves joined together to form a body having a fluid-tight cavity in its interior. The upper and lower surfaces of the disc each have a plurality of small suction cup-like projections molded thereon for frictionally engaging the adjacent vertebrae. The prosthesis is inserted within the intervertebral space and a volume of fluid is injected into the interior cavity of the prosthesis to create the necessary amount of resiliency which restores proper vertebral spacing.

10 More recently, emphasis has been placed on fusing bone structures (i.e., adjoining vertebrae) with prosthetic cage implants. One fusion cage implant is disclosed in commonly assigned U.S. Patent No. 5,026,373 to Ray et al.. The Ray '373 fusion cage includes a cylindrical cage body having a thread formed as part of its external surface and apertures extending through its wall which communicate with an internal cavity of the cage body. The fusion cage is inserted within a tapped bore or channel formed in the intervertebral space. The adjacent vertebral bone structures communicate through the apertures with bone growth inducing substances within the internal cavity to unite and eventually form a solid fusion of the adjacent vertebrae.

20 **SUMMARY**

Accordingly, the present disclosure is directed to further improvements in the fusion of adjacent bone structures, e.g., adjacent vertebrae. In a preferred embodiment, an implant for insertion within an intervertebral space between adjacent vertebrae for supporting the vertebrae in predetermined spaced relation is disclosed. The implant includes 25 lower and upper plate members dimensioned for at least partial insertion within the

intervertebral space and having contacting surfaces for engaging respective vertebral end faces of the adjacent vertebrae. A linkage mechanism including at least one link member operatively connects the lower and upper plate members. The linkage mechanism is actuatable to cause relative movement of the lower and upper plate members, wherein upon 5 actuation, the contacting surfaces of the lower and upper plate members engage the vertebral end faces with the lower and upper plate members supporting the adjacent vertebrae in spaced relation during healing. The linkage mechanism is preferably adapted to cause lateral displacing movement of at least one plate member upon actuation thereof such that contacting surfaces of the lower and upper plate members are in general parallel 10 relation when in the deployed position. Preferably, the contacting surfaces of the lower and upper plate members have discontinuities to engage the vertebral end plates. The discontinuities may be in the form of projections dimensioned for penetrating the vertebral end plates. The lower and upper plate members may further include at least one opening extending therethrough to permit bone ingrowth.

15 In another preferred embodiment, an implant for insertion within the intervertebral space includes first and second plate members having engaging surfaces with discontinuities to engage vertebral end faces of the vertebrae, and at least one resilient member disposed between the first and second plate members to bias the first and second plate members to a generally open spaced arrangement. The one resilient member is 20 configured and dimensioned to exert forces on the plate members sufficient to support the adjacent vertebrae in spaced relation during healing while permitting relative movement thereof to accommodate variations in loads realized during normal flexural movement of the vertebral column. Preferably, the one resilient member is a coil spring member. A plurality of coiled spring members may be incorporated as well.

In another preferred embodiment, an implant for insertion within the intervertebral space includes at least first and second supporting members dimensioned for insertion within the intervertebral space and having contacting surfaces for contacting vertebral end faces of the adjacent vertebrae. The first member has an inner arcuate articulating surface cooperating with a correspondingly dimensioned outer arcuate articulating surface of the second member to permit articulating movement of the first member so as to accommodate movement of the vertebral column during healing. Articulating surfaces of the first and second plate members each define a constant radius of curvature with the radius of curvature of each of the first and second plate members being substantially equal.

The contacting surfaces of the first and second plate members each include a plurality of apertures to permit bone ingrowth. A resilient member may be disposed between the first and second support members to facilitate the absorption of compressive forces.

In yet another preferred embodiment, the implant includes at least first and second support members having engaging surfaces for engaging vertebral end plates of the vertebrae, and a camming arrangement having at least one camming member operatively engageable with the first and second support members. The camming member is moveable to move the first and second support members between a non-deployed position and a deployed position. The camming member includes a camming block having a camming surface which is engageable with a corresponding camming surface of at least one of the support members whereby, upon movement of the camming member, the camming surfaces interact to move the first and second support members between the non-deployed and the deployed positions. An actuating screw transverses a bore defined in the camming block and threadably engages a threaded bore associated with one of the first and second

support members. The actuating screw is rotatable to cause corresponding movement of the camming block.

#### **BRIEF DESCRIPTION OF THE DRAWINGS**

5 Preferred embodiments of the disclosure are described hereinbelow with reference to the drawings wherein:

FIG. 1 is a perspective view of a preferred embodiment of the implant for facilitating spinal fusion constructed in accordance with the principles of the present disclosure;

10 FIG. 2 is a perspective view with parts separated of the implant of FIG. 1;

FIG. 3 is a perspective view of the implant in a collapsed position;

FIG. 4 is a view illustrating the implant in the collapsed position and inserted within an intervertebral space defined between adjacent vertebrae;

15 FIG. 5 is an isolated view further depicting the implant positioned within the intervertebral space;

FIG. 6 is a view similar to the view of FIG. 5 illustrating the implant in its extended position supporting the adjacent vertebrae in spaced relation;

FIG. 7 is a perspective view of an alternate embodiment of the implant of FIG. 1;

20 FIG. 8 is a perspective view with parts separated of the implant of FIG. 7 illustrating the first and second support members, support springs disposed between the support members and a flexible cover surrounding the support spring;

FIG. 9 is a sectional view illustrating the implant positioned within the intervertebral space;

FIG. 10 is an isolated view illustrating a preferred arrangement for mounting the flexible cover about the support members;

FIG. 11 is a view similar to the view of FIG. 9 illustrating the implant slightly compressed during normal flexural movement of the vertebral column;

5 FIG. 12 is a perspective view of another alternate embodiment of the spinal implant;

FIGS. 13-14 are perspective view of the respective upper and lower support members of the implant of FIG. 12 illustrating the ball and socket arrangement for permitting relative articulating movement of the support members;

10 FIG. 15 is a side plan view of the spinal implant of FIG. 12 in the assembled condition;

FIG. 16 is a sectional view illustrating the implant positioned within the intervertebral space;

15 FIG. 17 is a view similar to the view of FIG. 16 illustrating articulating movement of the upper support member via the ball and socket arrangement;

FIG. 18 is a side plan view of an alternate embodiment of the spinal implant of FIG. 12 incorporating a resilient layer disposed between the upper and lower support member;

20 FIG. 19 is a sectional view illustrating the implant of FIG. 18 positioned within the intervertebral space;

FIG. 20 is a view similar to the view of FIG. 19 illustrating articulating movement of the upper support member relative to the lower support member;

FIG. 21 is a perspective view of another alternate embodiment of the spinal implant;

FIG. 22 is a perspective view with parts separated of the implant of FIG. 21 illustrating the upper and lower support members, and the camming mechanism disposed between the support members for selectively moving the first and second support members between a retracted position and an extended position;

5 FIG. 23 is a sectional view illustrating the implant in the retracted position positioned within the intervertebral space;

FIG. 24 is a view similar to the view of FIG. 23 illustrating the implant in the extended position;

10 FIG. 25 is a side plan view of another alternate embodiment of the spinal implant;

FIG. 26 is a cross-sectional view taken along the lines 26-26 of FIG. 25; and

FIGS. 27-28 are views similar to the view of FIG. 26 illustrating adjusting motion of the implant during flexural movement of the vertebral column.

15

#### **DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT(S)**

The apparatus of the present disclosure is intended for fusing adjacent bone structures and has particular application in the spinal fusion of adjacent vertebrae subsequent to a discectomy procedure. The apparatus may be implanted using any 20 conventional surgical approach, e.g., anterior and/or posterior approaches, or may be implanted utilizing minimally invasive or endoscopic surgical techniques currently being utilized to carry out discectomy and spinal implant procedures.

Referring now to FIGS. 1-3, there is illustrated the apparatus constructed in accordance with the principles of the present disclosure. Apparatus 100 includes two 25 separable support components 102, 104 which are adapted for adjusting sliding movement

relative to each other to selectively vary the overall width of the implant. Support component 102 has upper and lower support plates 102u, 102l while support component 104 has upper and lower plates 104u, 104l. As shown, plates 102u, 102l of component 102 each have a greater width than plates 104u, 104l of component 104.

5       Upper and lower plate portions 102u, 102l of support component 102 each include two raised portions 106 extending generally transversely therefrom which define longitudinal slots 108. Upper and lower plates 104u, 104l each have two transverse tongue portions 110 extending therefrom which are correspondingly dimensioned to be received within transverse slots 108 to mount support component 104 to support 10 component 102. Tongue portions 110 are strategically dimensioned to slide within slots 108 thereby permitting selective adjusting movement of the component 104 relative to component 102. In this manner, the overall width of implant 100 may be varied to accommodate vertebral columns of various sizes or to increase or minimize the supporting capacity of the implant during healing. In particular, support components 102, 104 may be 15 selectively moved toward each other via the tongue and slot arrangement to decrease the overall width of the implant 100 thereby permitting more lateral movement of the vertebral column during healing. On the other hand, support components 102, 104 may be moved away from each other to increase the overall width of the implant thereby providing a more stabilizing effect to the vertebral column.

20       Referring still to FIGS. 1-3, upper plate portions 102u, 104u and lower plate portions 102l, 104l each possess associated outer contacting surfaces which engage the vertebral end faces. The contacting surfaces define discontinuities to assist in engaging the vertebral end faces upon insertion within the intervertebral space. Preferably, the discontinuities are in the form of triangular-shaped projections 112 extending from the 25 contacting surfaces, which define pointed edges to penetrate the vertebral end faces to

thereby resist tendency of the implant to move or become dislodged once positioned within the adjacent bone structures. Other discontinuities are envisioned as well such as knurling, bristle-coatings, etc... Upper plate portions 102u, 104u and lower plate portions 102l, 104l also include apertures 114, 116. Apertures 114, 116 permit bone ingrowth through 5 their respective plates to facilitate fusion of the implant with the vertebral bodies.

As best depicted in FIG. 1, linkage mechanism, identified generally by reference numeral 118, respectively operatively connects upper and lower plate portions 102u, 102l and upper and lower plate portions 104u, 104l. Each linkage mechanism 118 is preferably identical and includes transverse connecting links 120 connected to opposed 10 ends of upper plate portions 102u, 104u through pins 122 and transverse connecting links 124 connected to opposed ends of lower plate portions 102l, 104l through pins 126. Connecting links 120, 124 are interconnected by longitudinal links 128 through pins 130. Each linkage mechanism 118 is moveable between the extended position shown in FIG. 1 15 where upper and lower plate portions are at their most displaced position and a collapsed position shown in FIG. 3.

Referring now to FIGS. 4-5, the implant 100 is shown positioned within the intervertebral space "i" defined between adjacent vertebrae "V<sub>1</sub>, V<sub>2</sub>". Implant 100 is typically inserted within the intervertebral space "i" subsequent to a discectomy procedure. Discectomy involves removal of a least a portion of the degenerated disc material with the 20 use of the cutting instruments (not shown) e.g., scalpels, rongeurs, etc...

Prior to insertion, the width of implant 100 is adjusted by selectively adjusting the relative positioning of support components 102, 104 through the tongue and slot arrangement in the manner discussed above. Implant 100, in its collapsed condition, is thereafter positioned within the intervertebral space "i" with the use of a grasping 25 instrument (not shown). As mentioned, conventional anterior or posterior approaches, as

well as laparoscopic approaches, may be utilized. In the collapsed condition, implant 100 presents a reduced profile which facilitates its insertion. Once implant 100 is inserted and appropriately positioned, the linkage mechanisms 118 are actuated to displace upper plate portions 102u, 104u from lower plate portions 102l, 104l to move the implant to at least a  
5 partially extended position shown in FIG. 6. In this position, upper and lower plate portions 102u, 104u, 102l, 104l contact the vertebral end plates of the adjacent vertebrae in supporting engaged relation with triangular projections 112 of the plate portions penetrating the end plates to securely fix the implant member within the intervertebral space. In the deployed or extended position of FIG. 6, implant 100 forms a strut between adjacent  
10 vertebrae "V<sub>1</sub> V<sub>2</sub>" supporting the vertebrae in desired spaced relation. Linkage mechanisms 118 sufficiently support components 102,104 in the extended position. It is envisioned that linkage mechanisms 118 may be locked in the deployed position by conventional arrangements such as with locking screws, etc... As shown, upper plate portions 102u, 104u are in general parallel relation with lower plate portions 102l, 104l.  
15 Over a period of time, the adjacent vertebral tissue communicates through apertures 114, 118 defined in the support components 102, 104 to form a solid fusion.

It is envisioned that the interior cavity of implant 100 defined between the upper and lower plate portions may be packed with bone growth inducing substances as known in the art prior to insertion to facilitate the fusion process.

20 Referring now to FIGS. 7-8, there is illustrated an alternate embodiment of the spinal implant of the present disclosure. Implant 200 is intended to be used in a similar manner to that described in connection with implant 100 of FIG. 1, i.e., within the intervertebral space defined between adjacent vertebrae subsequent to a discectomy procedure. Implant 200 includes first and second plate members 202, 204 supported in  
25 spaced relation by a plurality of coiled support springs 206 which are disposed between the

plate members 202, 204. Springs 206 are received in correspondingly dimensioned impressions 208 defined in the inner surfaces of first and second plate members 202, 204 and extend in a generally transverse direction relative to each plate 202, 204 as shown. Support springs 206 permit deflecting movement, e.g., compressive movement of first and 5 second plate members 202, 204 to permit flexural compressive movement of the vertebral column. Springs 206 are correspondingly dimensioned to provide sufficient force to withstand extreme compressive forces exerted by the spinal column.

As best depicted in FIGS. 8-9, first plate 202 includes a plurality (e.g., four) of transversely extending rigid tubular portions 210. Second plate 204 includes a 10 plurality (e.g., four) of transversely extending rigid rod portions 212 extending from the inner surface thereof. Rod portions 212 are correspondingly dimensioned to be received within inner bores 214 defined by the tubular portions 210 to facilitate mounting of the first and second plate members 202, 204. In particular, the tubular portion 210 and rod portion 212 arrangement functions in preventing lateral movement of the first plate member 202 15 relative to the second plate member 204. The arrangement also serves in limiting the amount of compressive movement of plate members 202, 204 by engagement of the remote ends 210e of the tubular portions 210 with the inner surface of plate member 204. It is to be noted that tubular portions 210 are appropriately dimensioned to permit reciprocating movement of the rod portions 212 therein during compressive movement of the vertebral 20 column.

Referring to FIGS. 9-10, in conjunction with FIG. 8, a flexible cover 216 may be positioned about the periphery of implant 100 to enclose the coiled spring members 206. Cover 216 is preferably fabricated from a suitable biocompatible material. Cover 216 functions in preventing bone ingrowth from contacting the coiled support springs 206. 25 Bone ingrowth within support spring 206 may potentially degrade the functioning of

springs 206. Cover 216 is preferably mounted to upper and lower plate members 202, 204 through a tongue and groove arrangement shown in detail in FIG. 10. Preferably, the outer ends of flexible cover 216 define a tongue 218 which is accommodated within corresponding recesses 220 formed in first and second plate members 202, 204.

5 FIGS. 9 and 11 depict implant 100 positioned within the intervertebral space "i" defined between adjacent vertebrae "V<sub>1</sub> V<sub>2</sub>". FIG. 9 illustrates implant 100 in a fully extended position corresponding to a minimal load exerted on the vertebral column. FIG. 11 illustrates implant 100 in a compressed condition when the vertebral column is subjected to a large compressive load with support springs 206 absorbing the load. In 10 addition, in the inserted position of implant 200, pyramid-shaped projections 222 extending from the contacting surface 202, 204 penetrate the vertebral end plates of the "V<sub>1</sub>, V<sub>2</sub>" to facilitate mounting of the implant 200 within the intervertebral space "i", and to prevent the implant 200 from becoming dislodged prior to achieving full fusion with the adjacent vertebrae "V<sub>1</sub>, V<sub>2</sub>".

15 Referring now to FIGS. 12-17 there is illustrated another alternate embodiment of the spinal implant of the present disclosure. Spinal implant 300 includes first and second support members 302, 304 which supportingly engage adjacent vertebrae "V<sub>1</sub>, V<sub>2</sub>" upon insertion within an intervertebral space "i". Support member 302 includes a pair of parallel plates 306, 308 interconnected to each other through transverse side plate 20 portions 312 and transverse intermediate plate portion 314. Similarly, second support member 304 includes a pair of parallel plate portions 316, 318 interconnected by side plate portions 320 and intermediate plate portion 322. First support member 302 and second support member 304 are preferably each integrally formed to form a single unit and may be fabricated from a ceramic material, a biocompatible metallic material or a biocompatible 25 polymeric material. The respective upper and lower plate portions 306, 318 of first and

second support members 302, 304 have tissue contacting surfaces which define discontinuous surfaces to permit bone ingrowth during fusion. In a preferred embodiment, the discontinuous surfaces include a plurality of apertures 324 which permit bone ingrowth and a plurality of projections 326 which are disposed on a peripheral area of the respective 5 plate portions. Projections 326 define penetrating tip portions which engage the vertebral end plate upon application within the intervertebral space.

Referring now to FIGS. 13-15, first and second support members 302, 304 are supported in general spaced relation by a ball and socket arrangement. In particular, first support member 302 has an integrally formed spherical portion 328 extending from 10 lower plate 308. Second support member 304 has a projecting portion 330 extending from upper plate 316 and defining a generally spherical recess or socket 332 correspondingly dimensioned to accommodate spherical portion 328 of first support member 302. Spherical portion 328 is capable of articulating movement within socket 332 thereby permitting the vertebral column to flex through a generally "normal" range of motion. Preferably, 15 spherical portion 328 and socket 332 define generally equivalent radii of curvatures.

FIGS. 16 and 17 depict spinal implant 300 disposed within the intervertebral space "i" defined between adjacent vertebrae "V<sub>1</sub>, V<sub>2</sub>". As shown in FIG. 16, implant 300 supportingly contacts the upper and lower vertebrae "V<sub>1</sub>, V<sub>2</sub>" through the engagement of first support member 302 and second support member 304 with the 20 vertebral end faces. Projections 326 extending from the upper and lower plate portions 316, 318 of first and second support members 302, 304 penetrate the vertebral end faces to assist in retaining the implant 300 within the intervertebral space "i" during healing.

FIG. 17 illustrates the articulating movement of the first support member 302 relative to the second support member 304 during movement of the spine. As shown, 25 spherical portion 328 slides within socket 332 to permit such articulating movement.

FIGS. 18-20 depict an alternate embodiment of the spinal implant 300 of FIGS. 12-17. This embodiment is similar in most respects to the implant 300, but, further incorporates a resilient layer 350 disposed between first and second support members 302, 304. Resilient layer 350 is preferably a sponge like material and serves to provide a cushion between first and second support members 302, 304 and the adjacent vertebrae "V<sub>1</sub>, V<sub>2</sub>" to accommodate compressive forces realized by the vertebral column during movement as depicted in FIG. 20.

Referring now to FIGS. 21-24, there is illustrated another alternate embodiment of the spinal implant of the present disclosure. Implant 400 includes two support members, i.e., upper support member 402 and lower support member 404 having respective contacting surfaces 406, 408. Each contacting surface 406, 408 has a plurality of pyramid-shaped projections 410 which facilitate engagement with the vertebral end plates of the adjacent vertebrae "V<sub>1</sub>, V<sub>2</sub>" upon insertion within the intervertebral space "i". Implant 400 further includes a camming arrangement for moving upper and lower support members 402, 404 between an open and a closed position. The preferred camming arrangement includes a camming block 412 which is adapted for traversing movement within the interior of implant 400. Camming block 412 defines an inclined camming surface 414 which engages a correspondingly dimensioned inner surface 416 of support member 402. The camming arrangement further includes a threaded element, e.g., screw 418, which traverses a bore 420 within camming block 412 and threadably engages an internal threaded bore 422 of lower support member 404.

Support members 402, 404 are interconnected through a pin and slot arrangement. More particularly, support member 402 has a pair of transversely extending slots 424 formed in side plates 426. Support member 404 has a pair of correspondingly positioned apertures 428 formed in side plates 430. A pin 432 traverses each slot and

opening arrangement to connect upper support member 402 and lower support member 404.

FIGS. 23-24 illustrate rotational movement of screw 418 and the consequent corresponding traversing movement of camming block 412. In particular, rotation of screw 418 in a clockwise direction causes the screw to advance within threaded bore 422 thereby advancing camming block 412 in the direction indicated by the directional arrow in FIG. 24 and displacing upper support member 402 from lower support member 404. As upper support member 402 moves relative to lower support member 404, pins 432 traverse slots 424 of upper support member 402.

Referring now to FIGS. 25-28, another alternate embodiment of the present disclosure is illustrated. Implant 500 includes upper and lower support members 502, 504 and at a resilient layer 506 disposed between the support members 502, 504. Each support member 502, 504 includes first and second plate members 508, 510. First and second plate members 508, 510 are interconnected by peripheral interconnecting members 512, 514 and intermediate interconnecting member 516. An internal cavity 518 is defined between the plate members 508, 510. Support members 502, 504 are each preferably integrally formed to form a single component as shown.

First plate member 508 has a plurality of apertures 520 extending therethrough in communication with internal cavity 518 to promote bone ingrowth to facilitate the fusion process. A plurality of triangular-shaped projections 522 or teeth extend from the first plate member 508 and are dimensioned to penetrate the vertebral end faces to facilitate retention of the implant 500 within the intervertebral space. First plate member 510 of support member 504 is preferably inclined relative to axis "a" of the implant. This inclined configuration provides.

Resilient layer 506 disposed between plate members 508, 510 is preferably formed of a resilient material such as synthetic rubber or other elastomeric material. Resilient layer 506 provides sufficient forces to maintain the adjacent vertebrae in spaced relation while permitting relative flexural compressive movement of the vertebral column as depicted in FIGS. 27-28. Alternately, instead of resilient layer 506, compression springs, covered by a flexible film so as not to interfere with surrounding tissue, could be positioned between the upper and lower support member. Parallel pins to provide shear strength can be positioned adjacent the springs spanning the space between the upper and lower supports.

While the above description contains many specifics, these specifics should not be construed as limitations on the scope of the disclosure, but merely as exemplifications of preferred embodiments thereof. Those skilled in the art will envision many other possible variations that are within the scope and spirit of the disclosure as defined by the claims appended hereto.

**WHAT IS CLAIMED IS:**

1. An implant for insertion within an intervertebral space between adjacent vertebrae for supporting the vertebrae in predetermined spaced relation, which comprises:

5 lower and upper plate members dimensioned for at least partial insertion within the intervertebral space defined between adjacent vertebrae, the lower and upper plate members having contacting surfaces for engaging respective vertebral end faces of the adjacent vertebrae; and

10 a linkage mechanism including at least one link member operatively connecting the lower and upper plate members, the linkage mechanism actuatable to cause relative movement of the lower and upper plate members, wherein upon actuation, the contacting surfaces of the lower and upper plate members engage the vertebral end faces with the lower and upper plate members supporting the adjacent vertebrae in spaced relation during healing.

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2. The prosthetic implant according to claim 1 wherein the linkage mechanism is adapted to cause lateral displacing movement of at least one plate member upon actuation thereof such that the contacting surfaces of the lower and upper plate members are in general parallel relation when in the deployed position.

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3. The prosthetic implant according to claim 2 wherein the contacting surfaces of the lower and upper plate members have discontinuities to engage the vertebral end plates.

4. The prosthetic implant according to claim 3 wherein the discontinuities are projections dimensioned for penetrating the vertebral end plates.

5. The prosthetic implant according to claim 3 wherein the lower and upper plate members each include at least one opening extending therethrough to permit bone ingrowth.

10 6. The prosthetic implant according to claim 1 wherein each of the lower and upper plate members include first and second plate portions, the first and second plate portions being relatively moveable such that the width of each plate member is selectively adjustable.

15 7. The prosthetic implant according to claim 6 including two linkage mechanisms, a first of the linkage mechanisms interconnecting the first plate portions of the lower and upper support members, a second of the linkage mechanisms interconnecting the second plate portions of the first and second support members.

20 8. The prosthetic implant according to claim 7 wherein the first and second plate portions are connected through a tongue and slot arrangement, the tongue and slot arrangement adjustable to permit relative movement of the first and second plate portions.

25 9. An implant for insertion within an intervertebral space between adjacent vertebrae for supporting the vertebrae in spaced relation during healing, which comprises an implant member including first and second support components, the support

components being operatively connected and moveable relative to each other to selectively adjust the effective width of the implant member, each support component including upper and lower plate portions with contacting surfaces for engaging respective vertebral end faces of the adjacent vertebrae.

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10. An implant for insertion within an intervertebral space defined between adjacent vertebrae, comprising first and second plate members dimensioned for insertion within the intervertebral space, the first and second plate members having engaging surfaces with discontinuities to engage vertebral end faces of the vertebrae, and at least one resilient member disposed between the first and second plate members to bias the first and second plate members to a generally open spaced arrangement, the one resilient member configured and dimensioned to exert forces on the plate members sufficient to support the adjacent vertebrae in spaced relation during healing while permitting relative movement thereof to accommodate variations in loads realized during normal flexural movement of the vertebral column.

15. The implant according to claim 10 wherein the resilient member is a coil spring member.

20. The implant according to claim 11 including a plurality of coiled spring members disposed between the plate members.

25. The implant according to claim 12 including a flexible cover surrounding the spring members to prevent bone ingrowth within the spring members.

14. The implant according to claim 10 wherein the resilient member includes a resilient layer.

15. An implant for insertion within an intervertebral space defined between adjacent vertebrae for supporting the vertebrae in predetermined spaced relation during healing which comprises at least first and second supporting members dimensioned for insertion within the intervertebral space and having contacting surfaces for contacting vertebral end faces of the adjacent vertebrae, the first member having an inner arcuate articulating surface cooperating with a correspondingly dimensioned outer arcuate articulating surface of the second member to permit articulating movement of the first member to accommodate movement of the vertebral column during healing.

16. The implant according to claim 15 wherein the contacting surfaces of the first and second plate members each include a plurality of apertures to permit bone ingrowth.

17. The implant according to claim 15 wherein the articulating surfaces of the first and second plate members each define a constant radius of curvature, the radius of curvature of each of the first and second plate members being substantially equal.

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18. The implant according to claim 15 further including a resilient member disposed between the first and second support members.

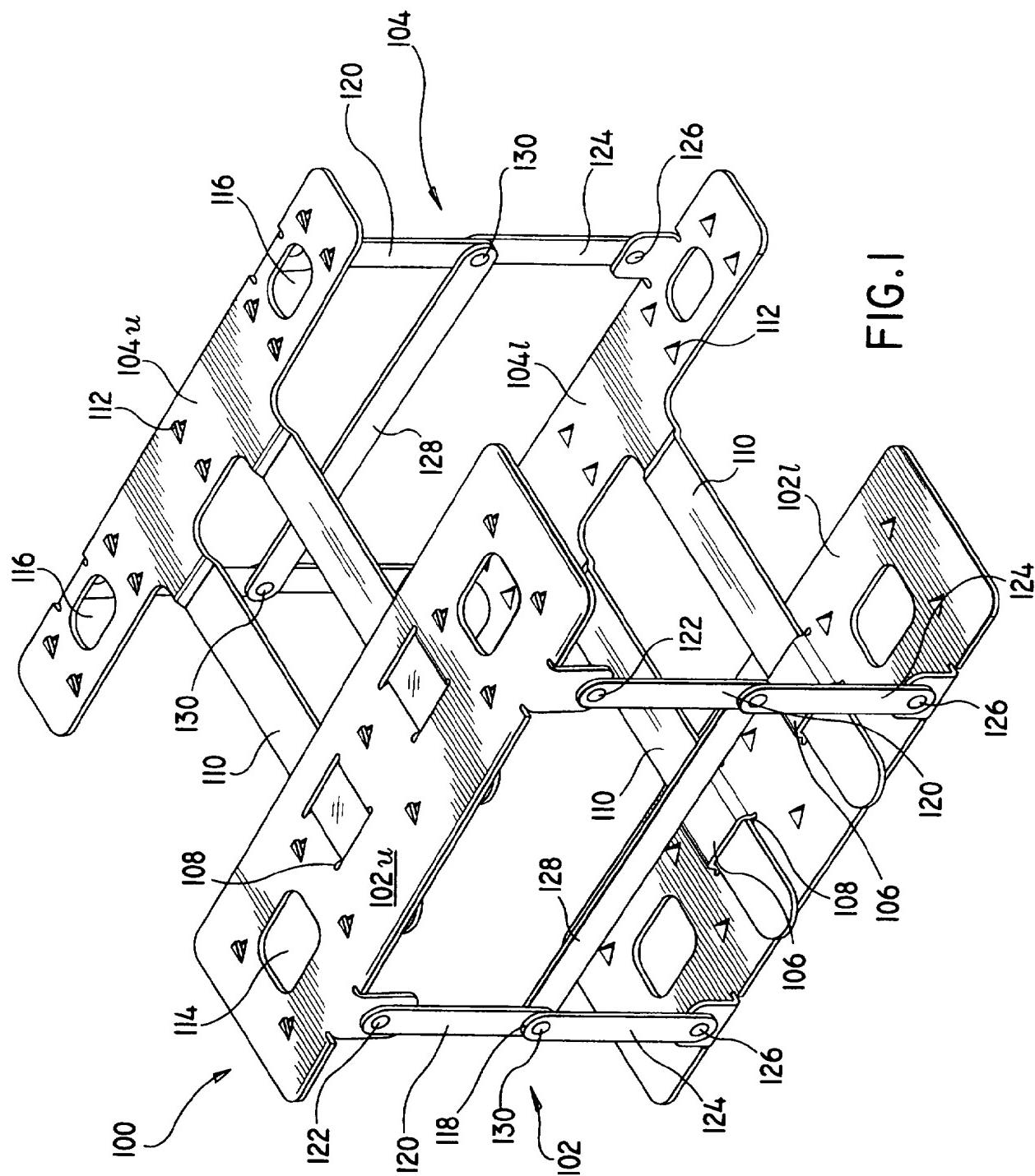
19. The implant according to claim 18 wherein the resilient member includes a layer of sponge-like material.

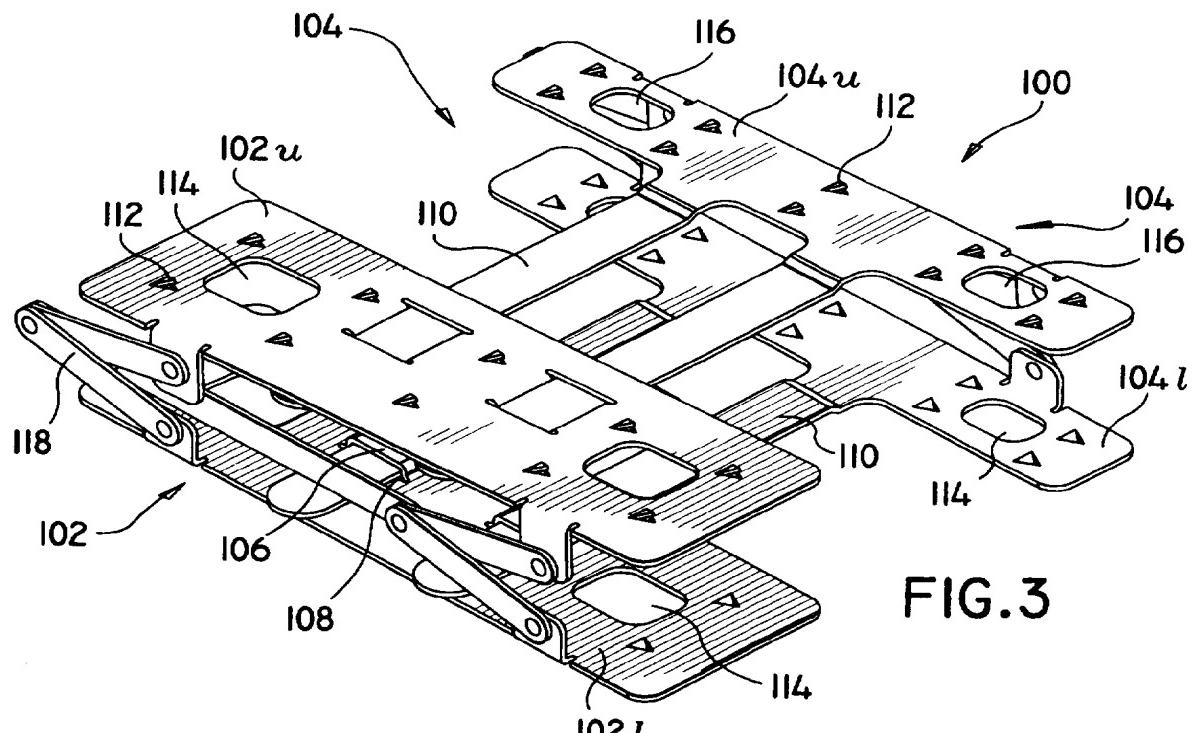
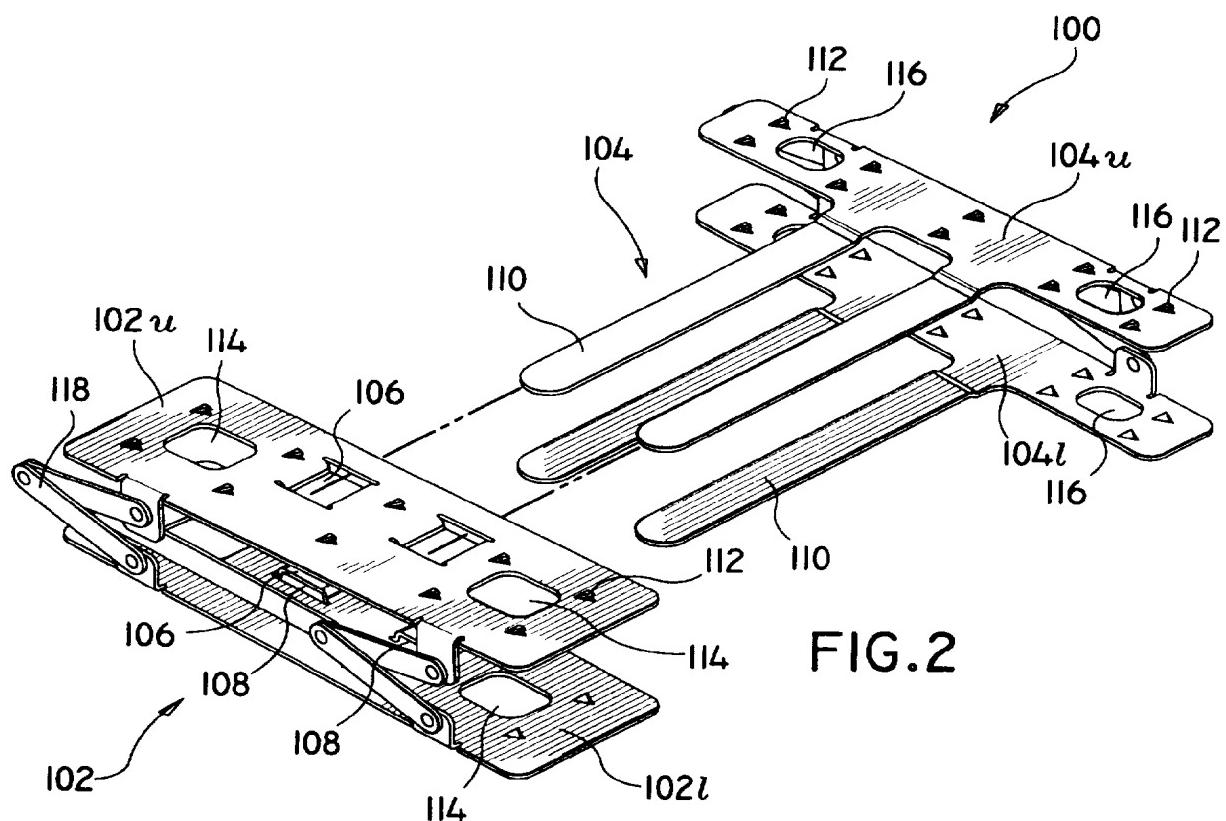
20. An implant for insertion within an intervertebral space defined between adjacent vertebrae for supporting the vertebrae in predetermined spaced relation during healing, which comprises at least first and second support members dimensioned  
5 for insertion within the intervertebral space defined between adjacent vertebrae and having engaging surfaces for engaging vertebral end plates of the vertebrae, and a camming arrangement having at least one camming member operatively engageable with the first and second support members, the camming member moveable to move the first and second support members between a non-deployed position and a deployed position.

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21. The implant according to claim 20 wherein the camming member includes a camming block having a camming surface, the camming surface engageable with a corresponding camming surface of at least one of the support members whereby upon movement of the camming member the camming surfaces interact to move the first and  
15 second support members between the non-deployed and the deployed positions.

22. The implant according to claim 21 including an actuating screw transversing a bore defined in the camming block and threadably engaging a threaded bore associated with one of the first and second support members, the actuating screw rotatable  
20 to cause corresponding movement of the camming block.





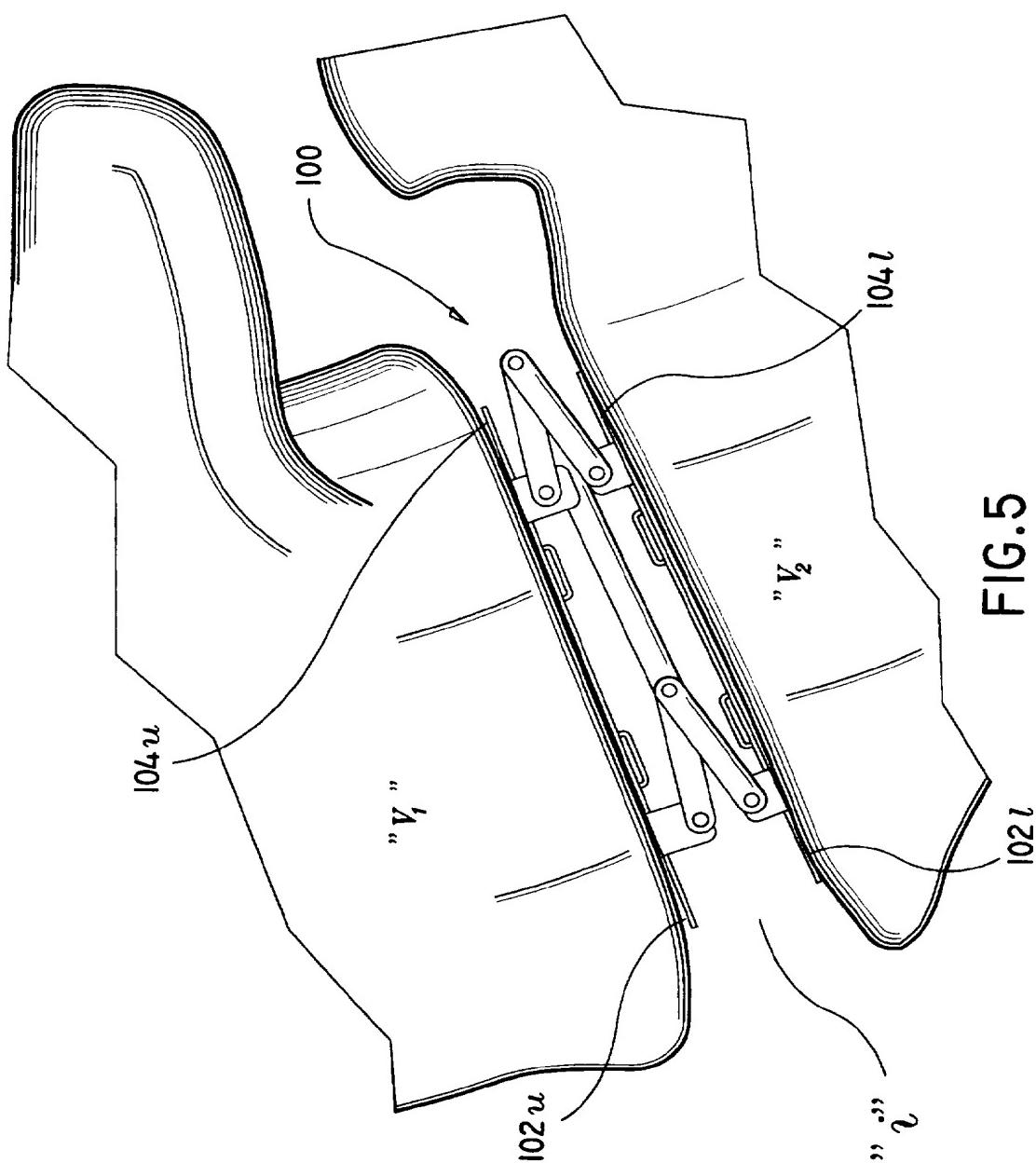
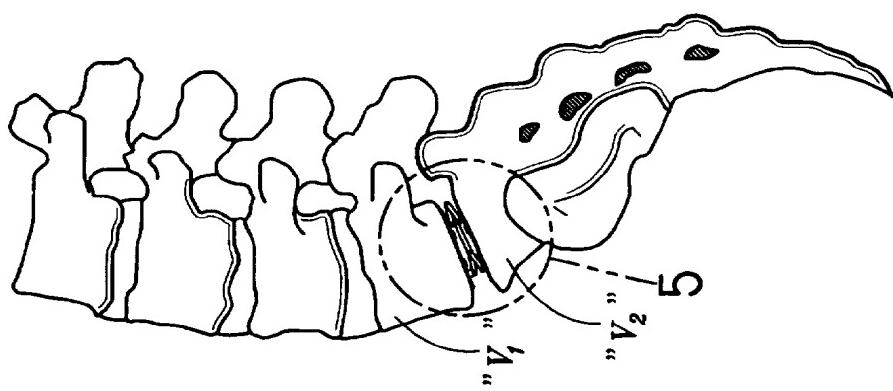
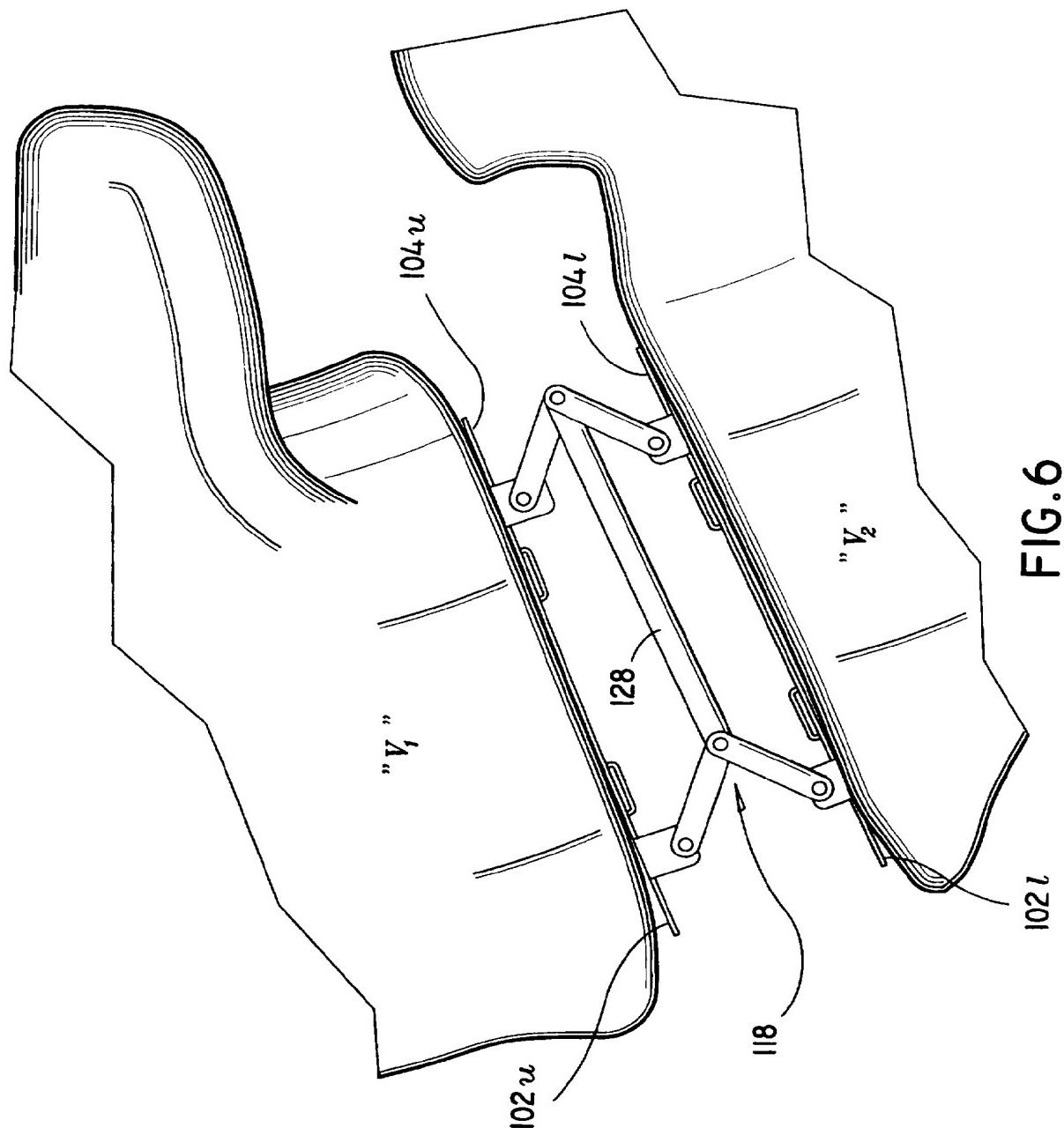
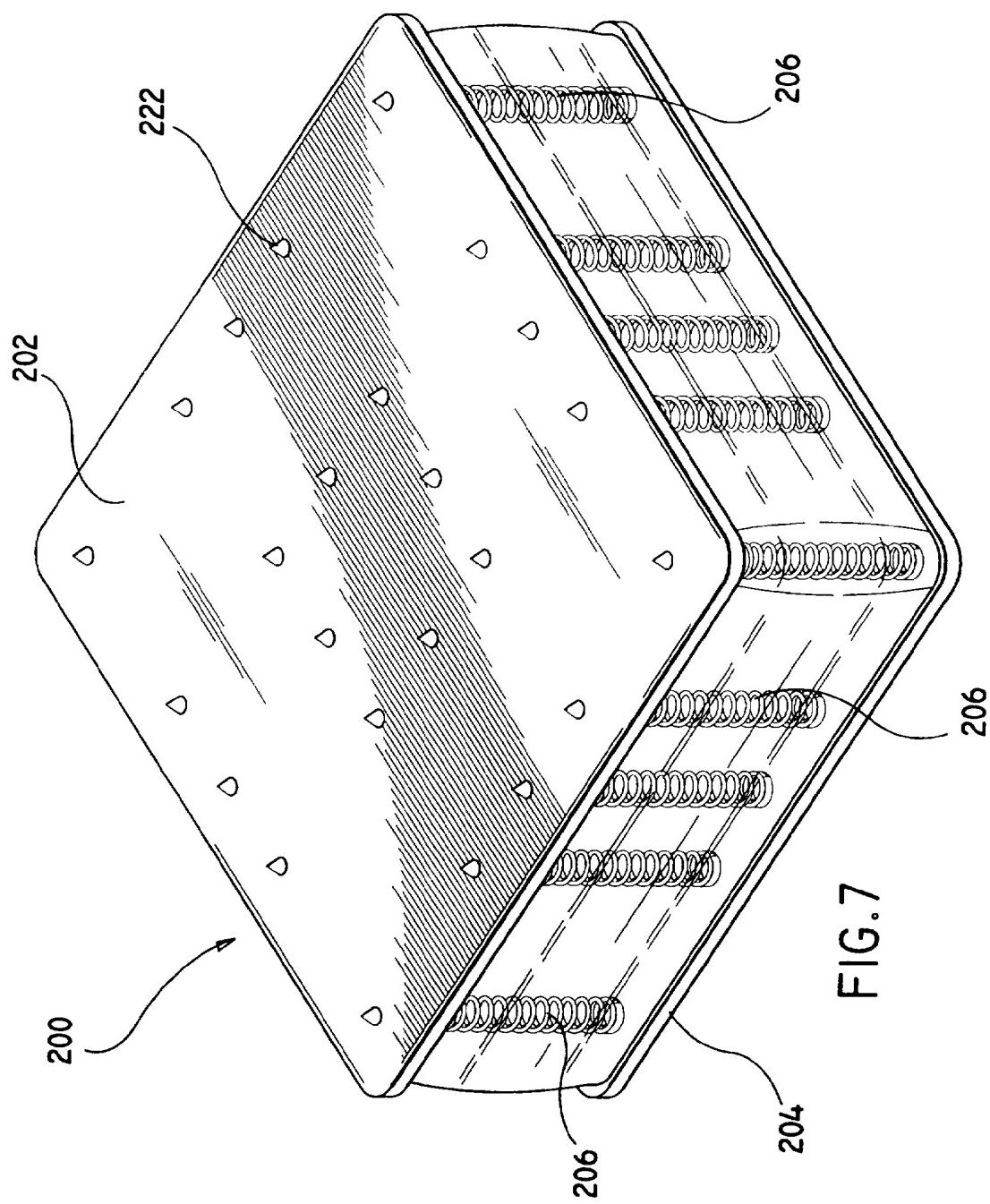
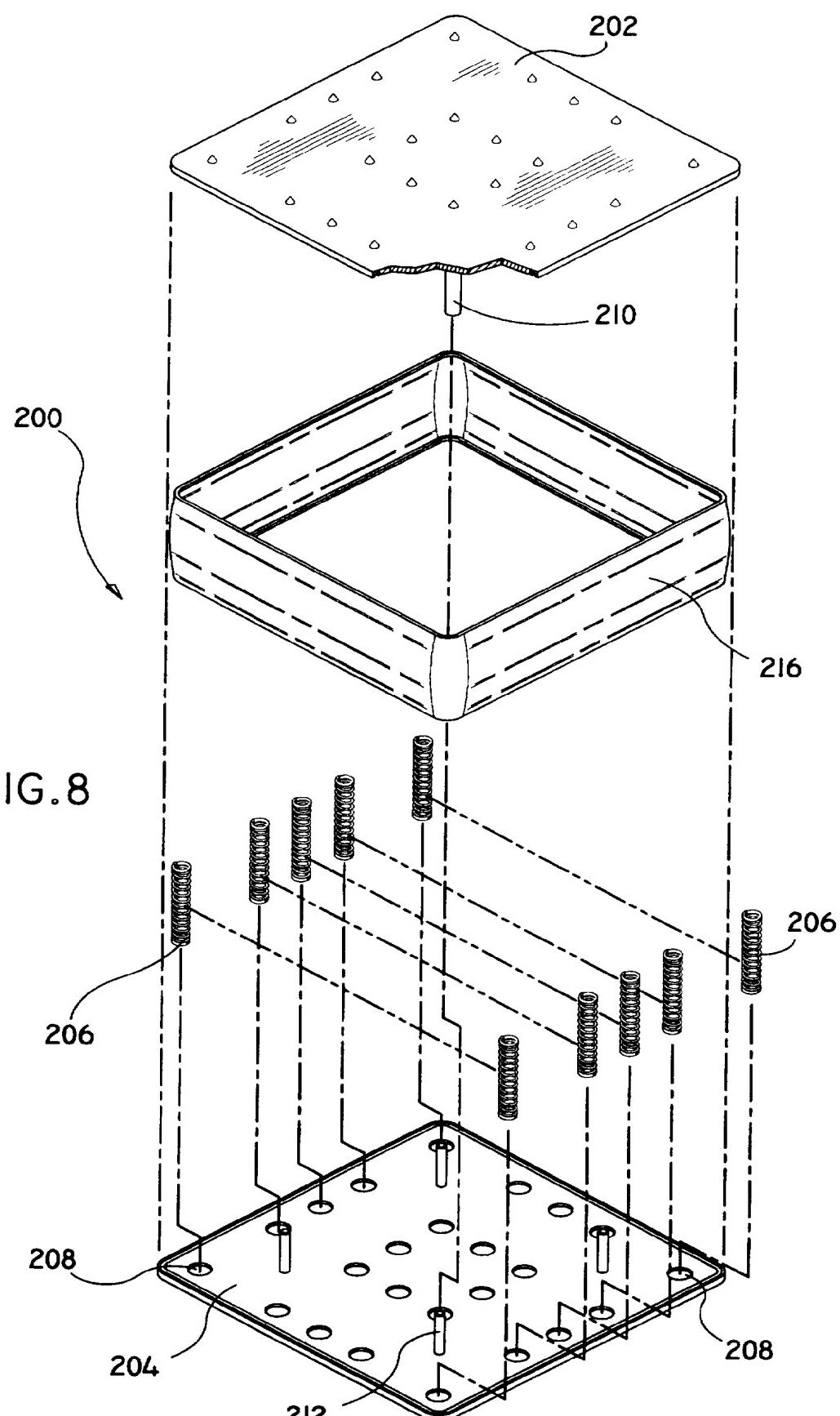


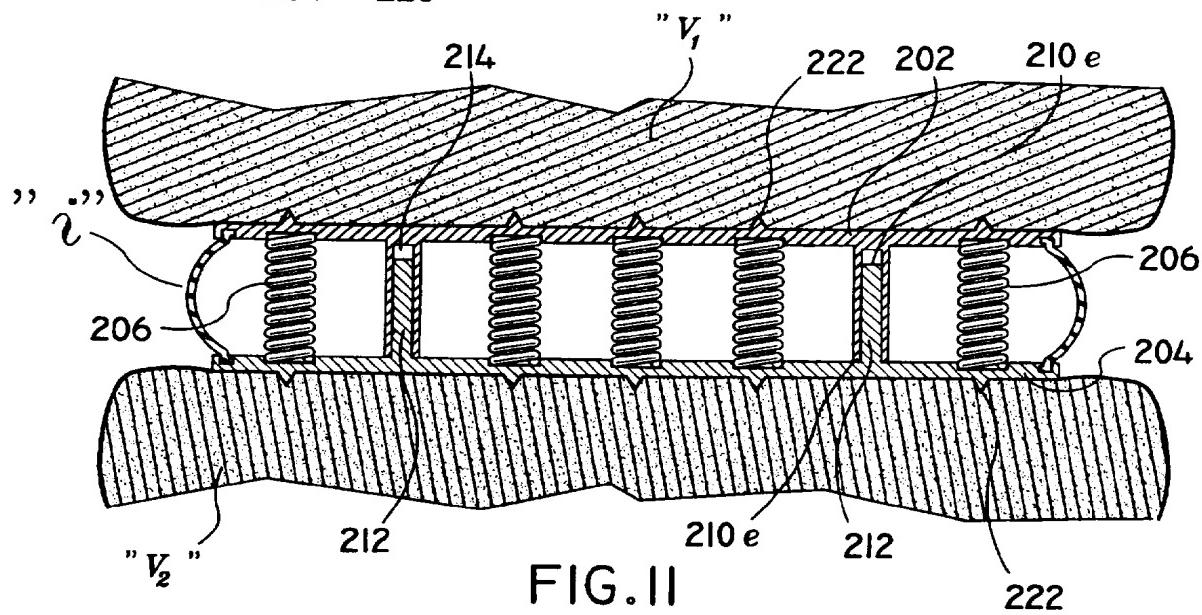
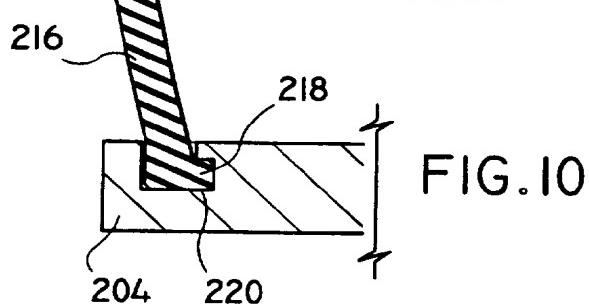
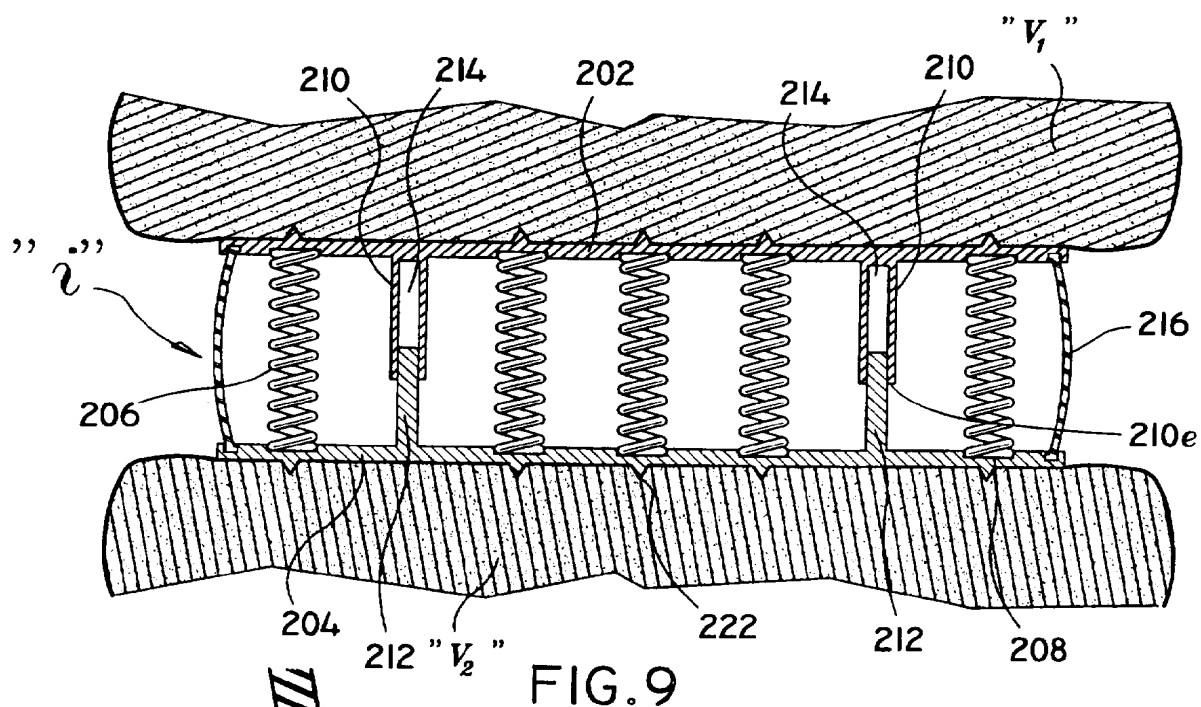
FIG. 4

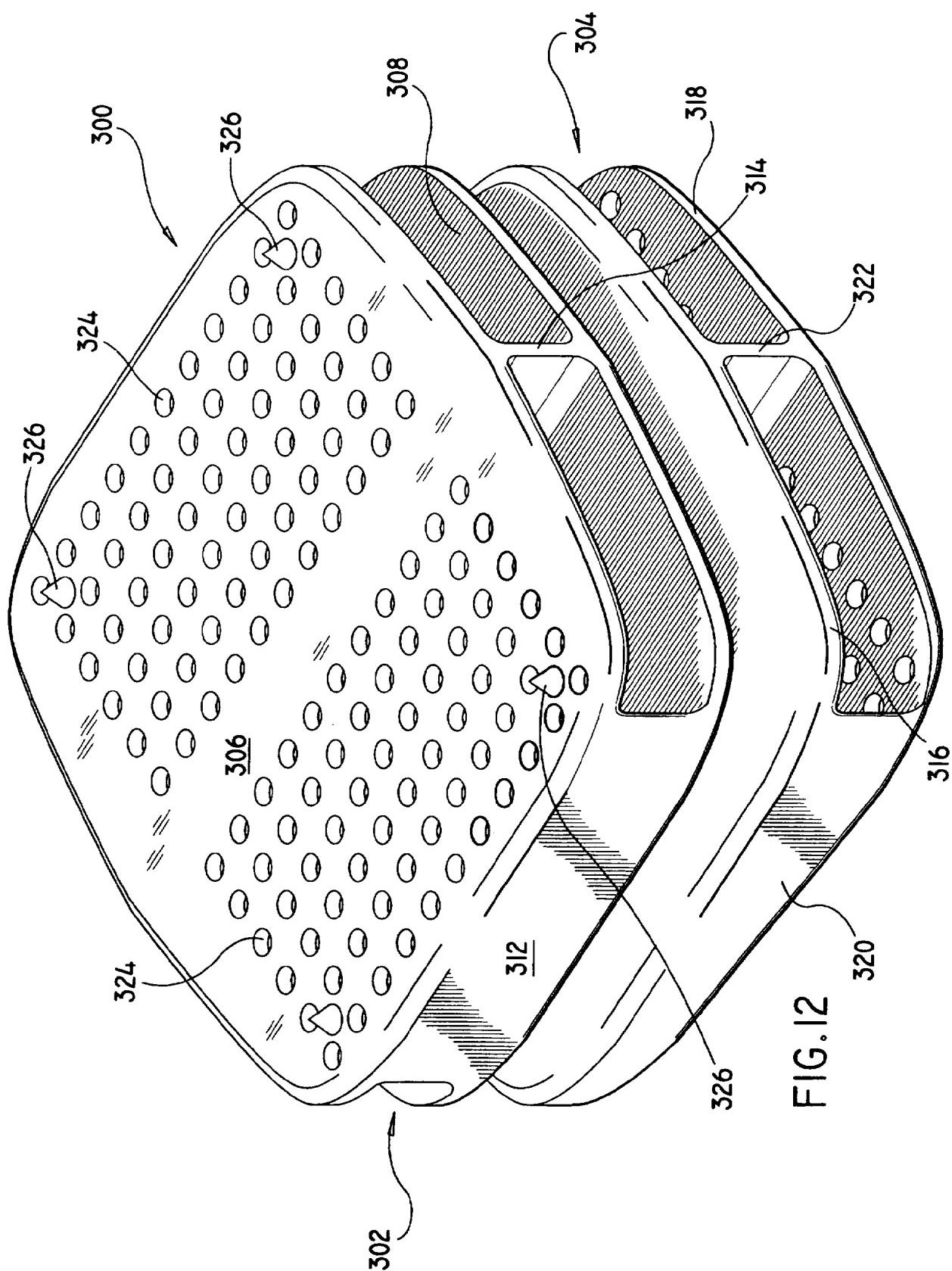












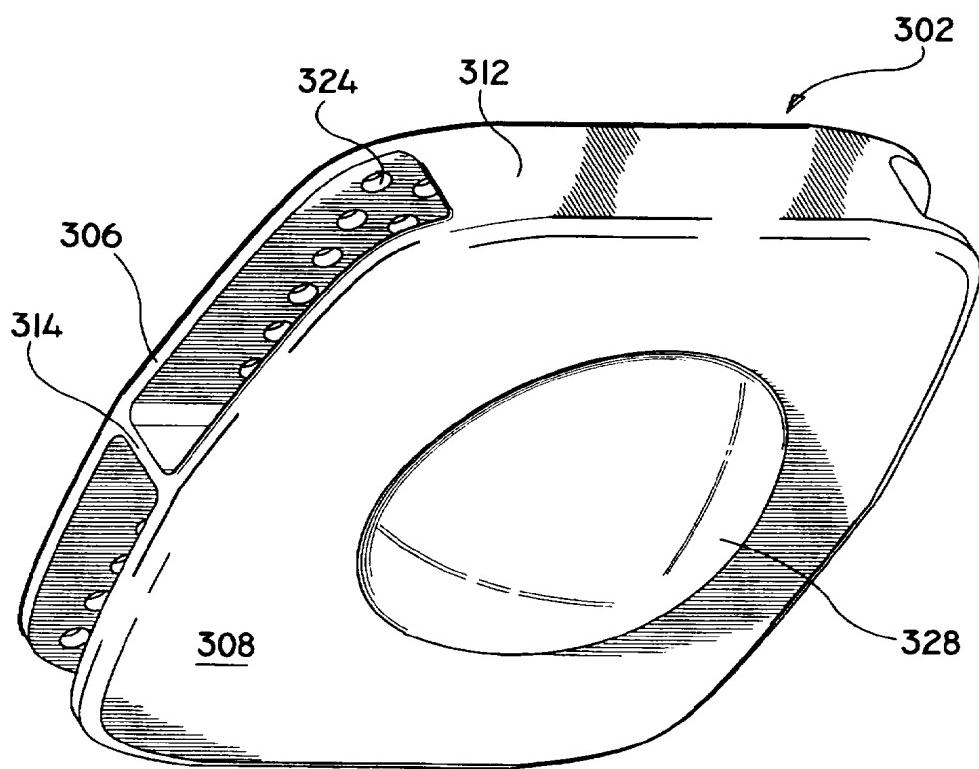
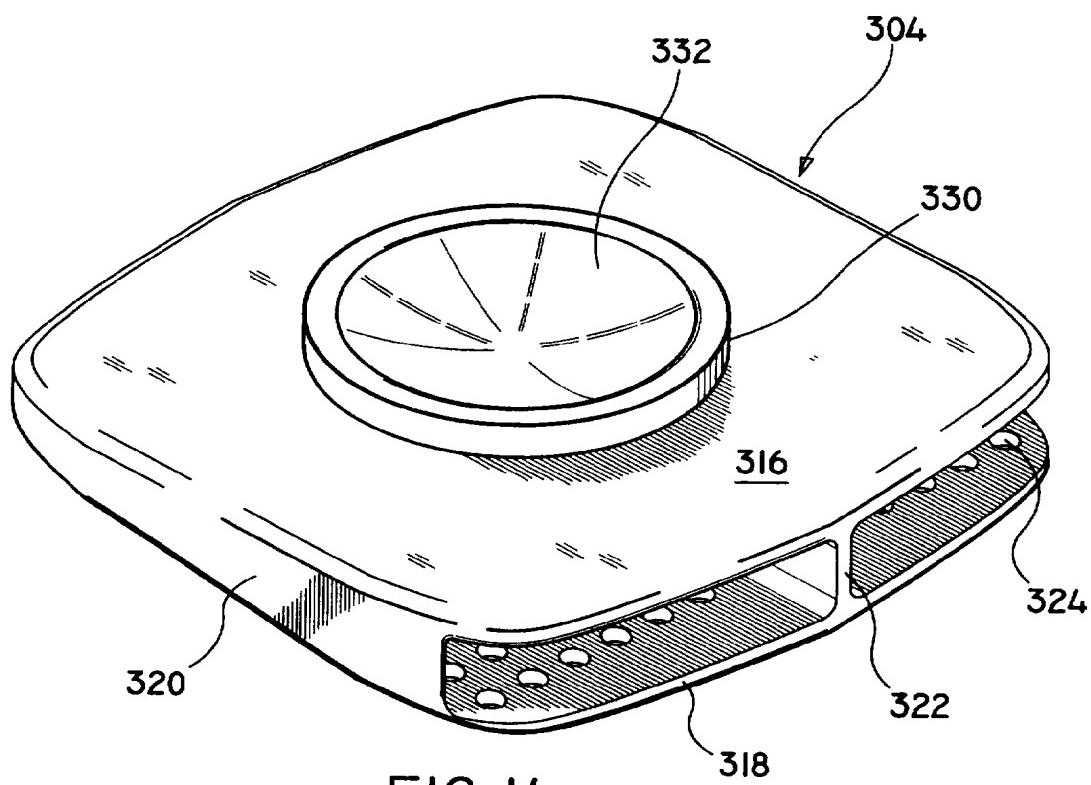
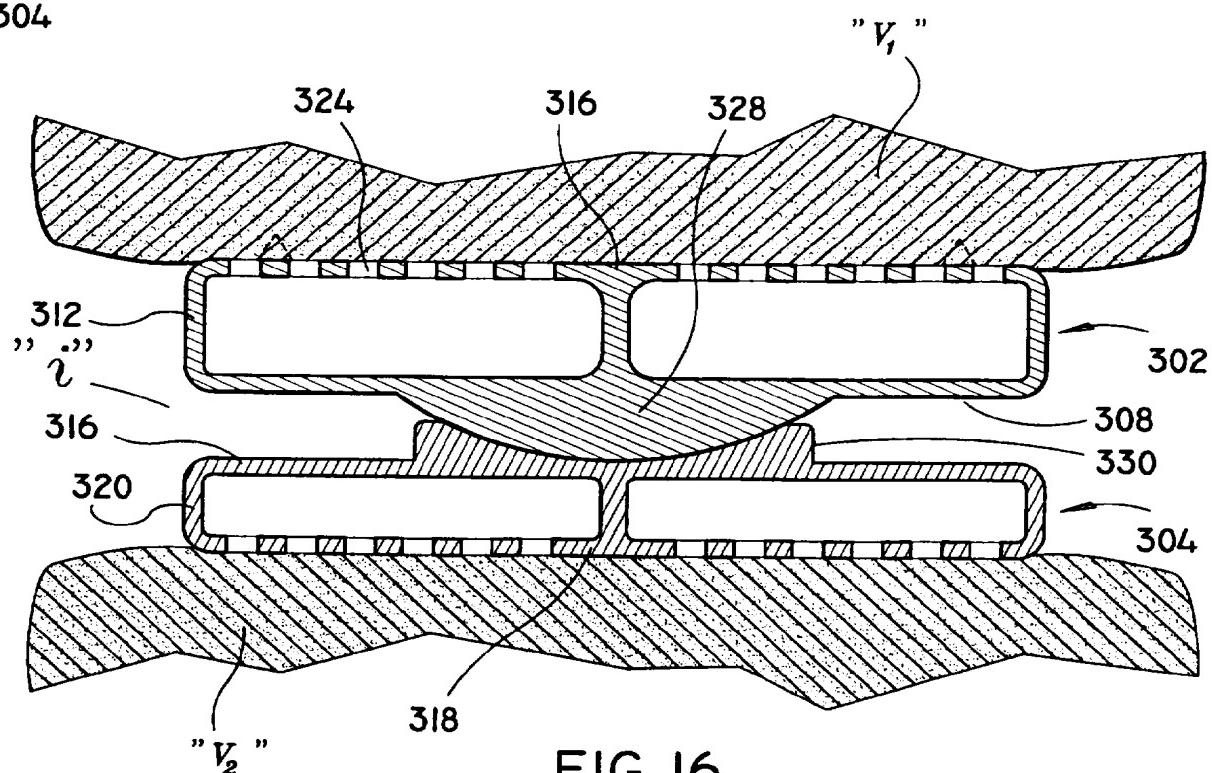
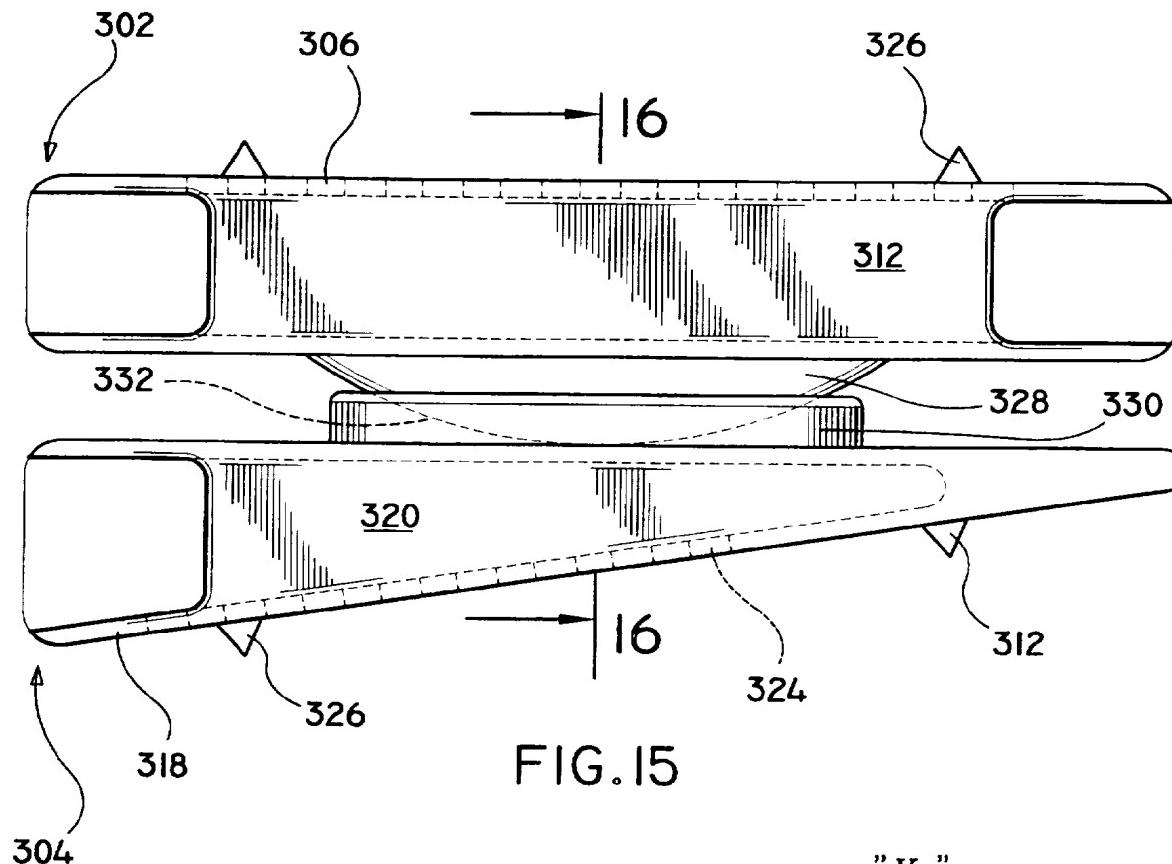


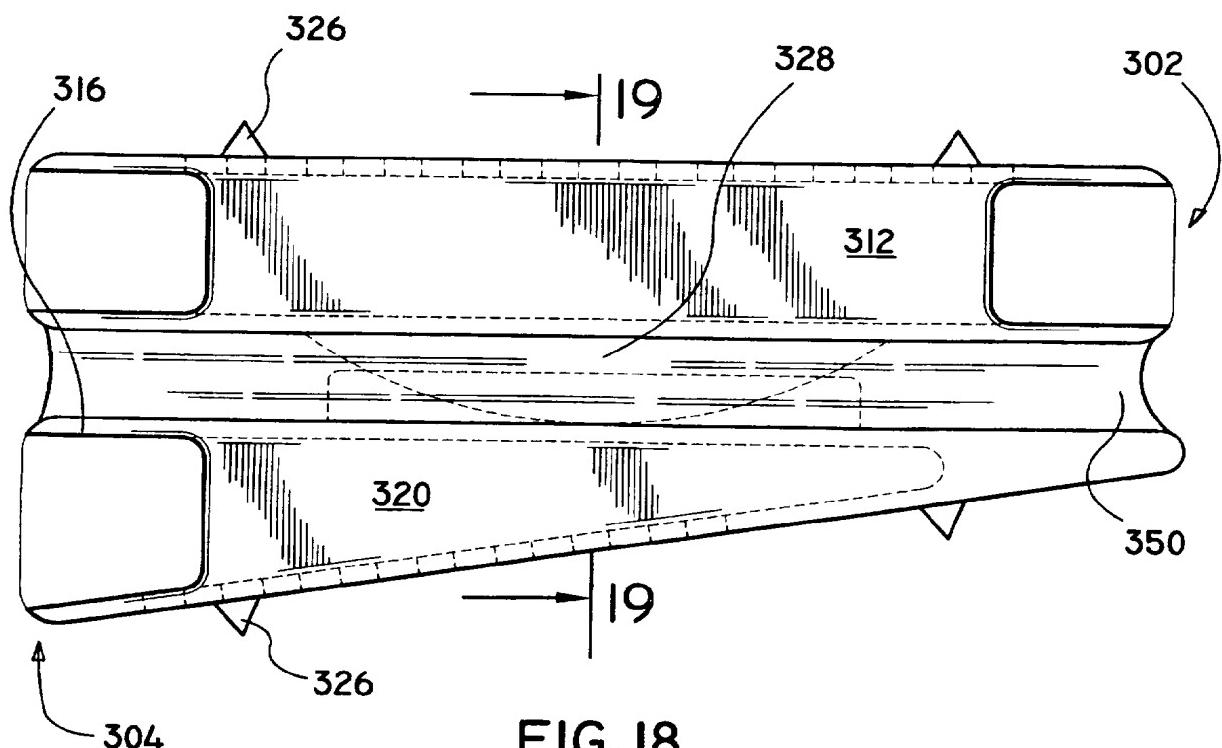
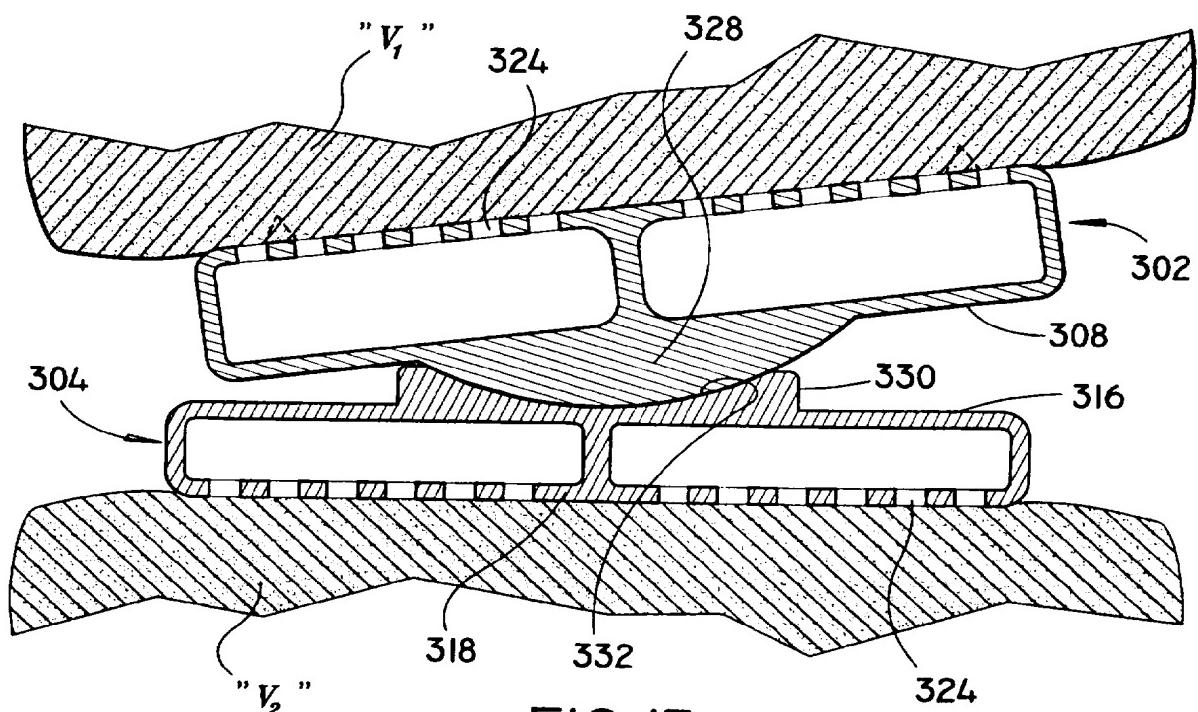
FIG.13

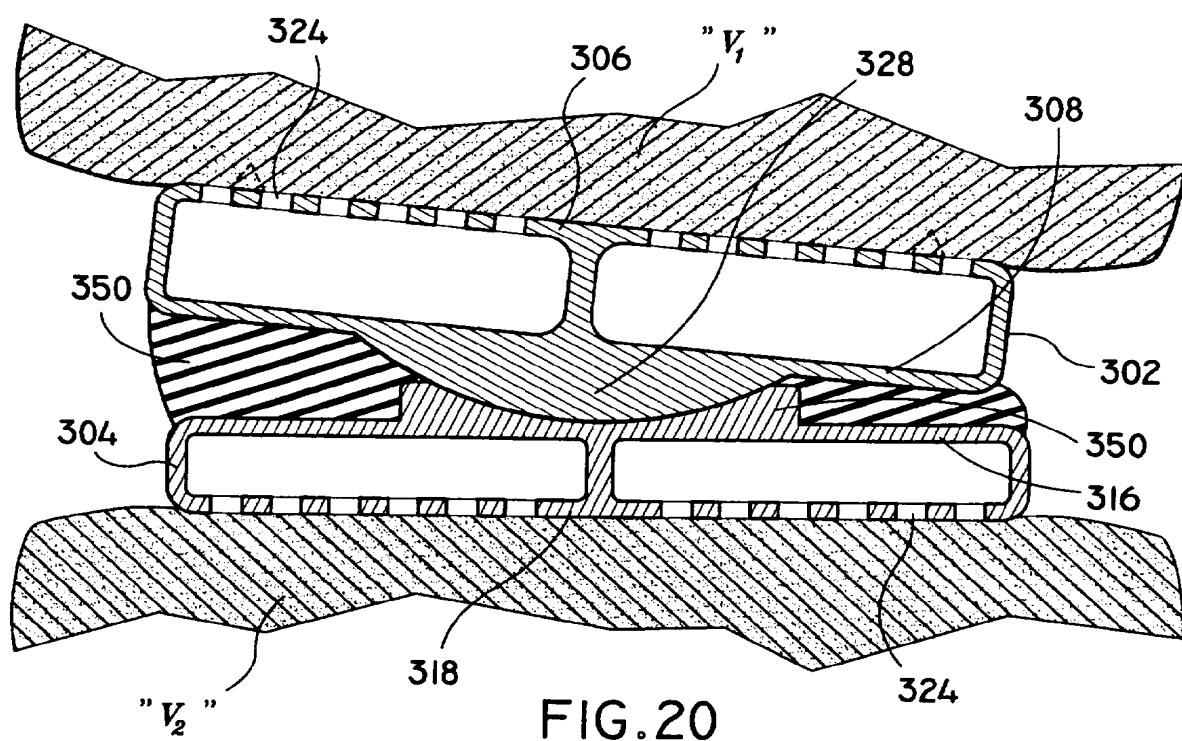
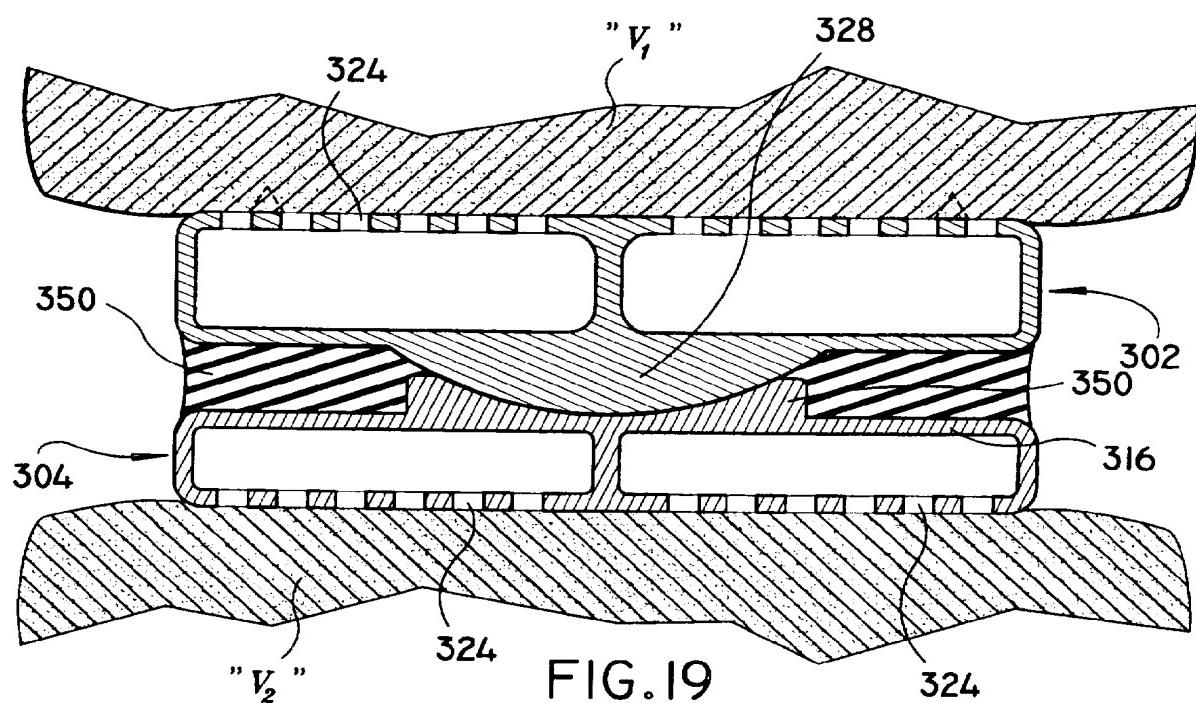
FIG.14  
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SUBSTITUTE SHEET (RULE 26)





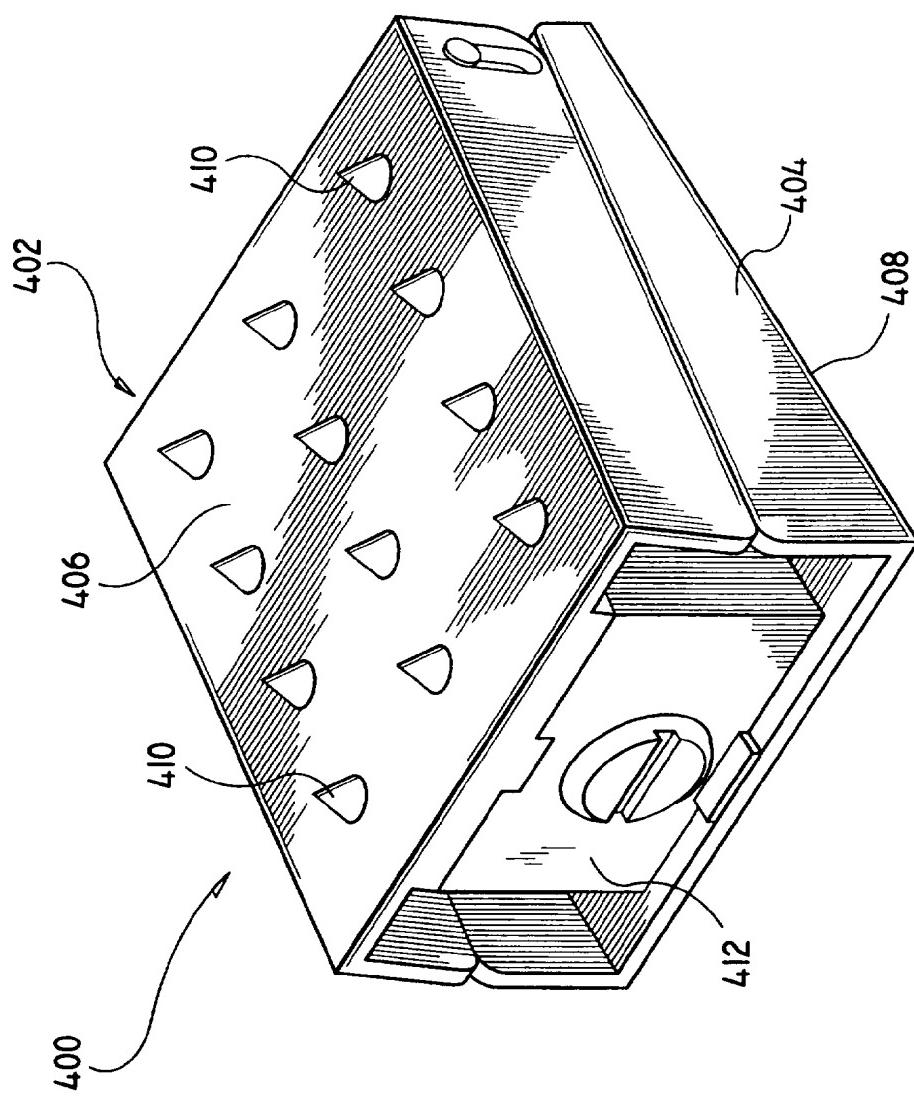
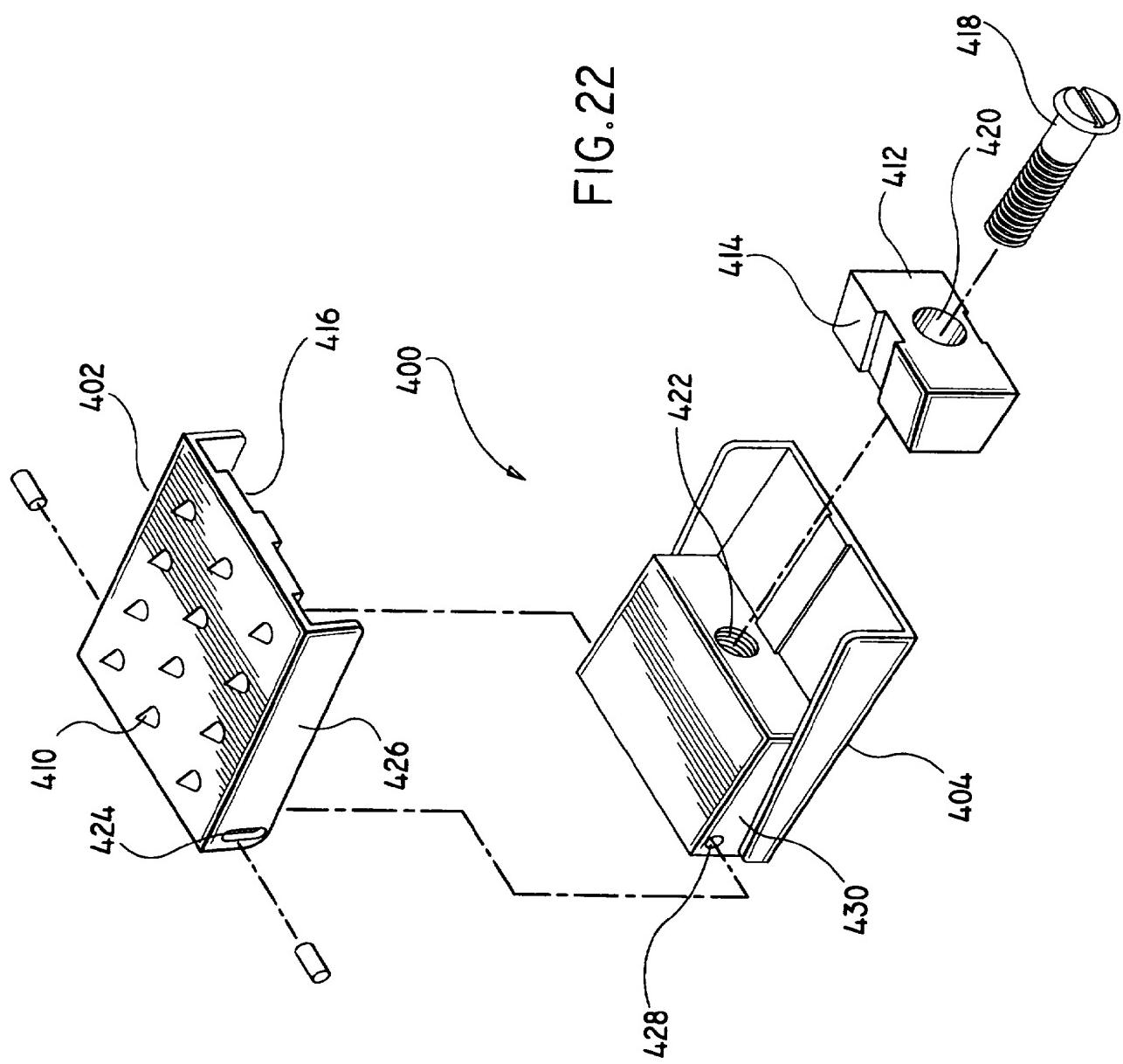
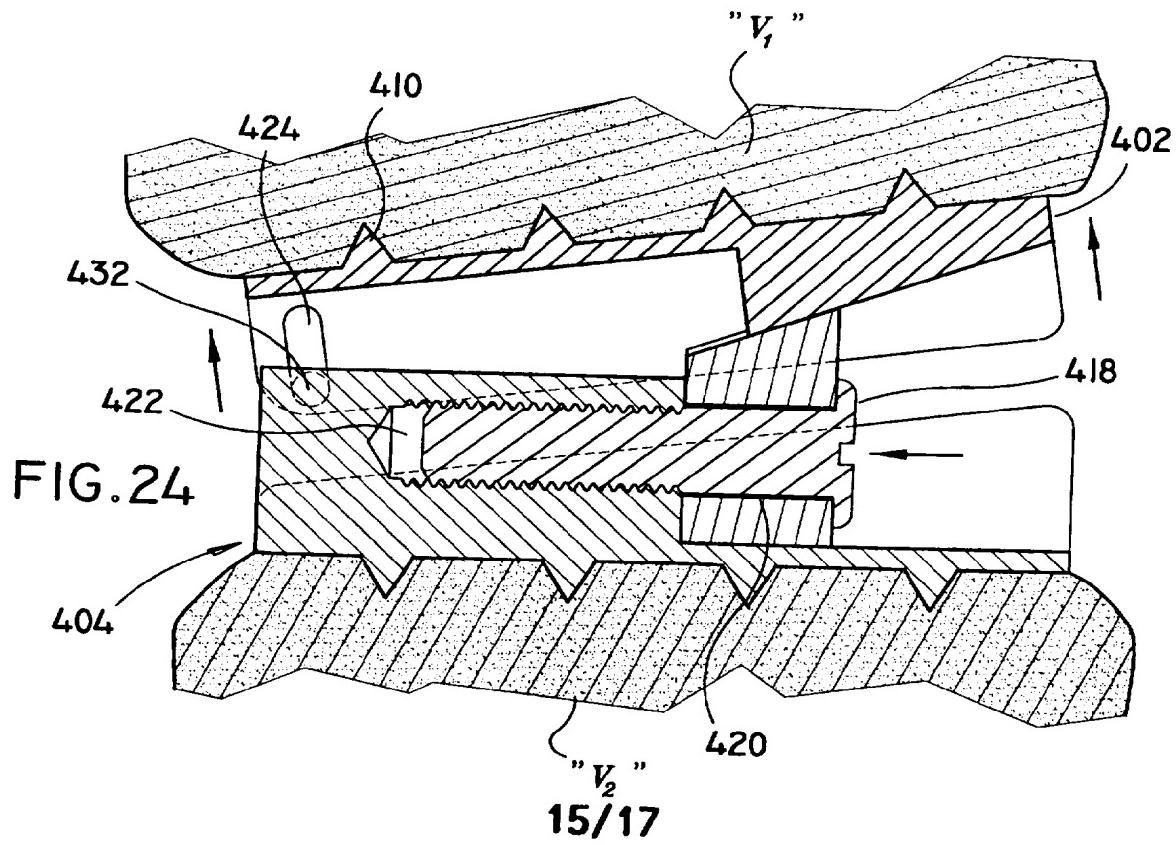
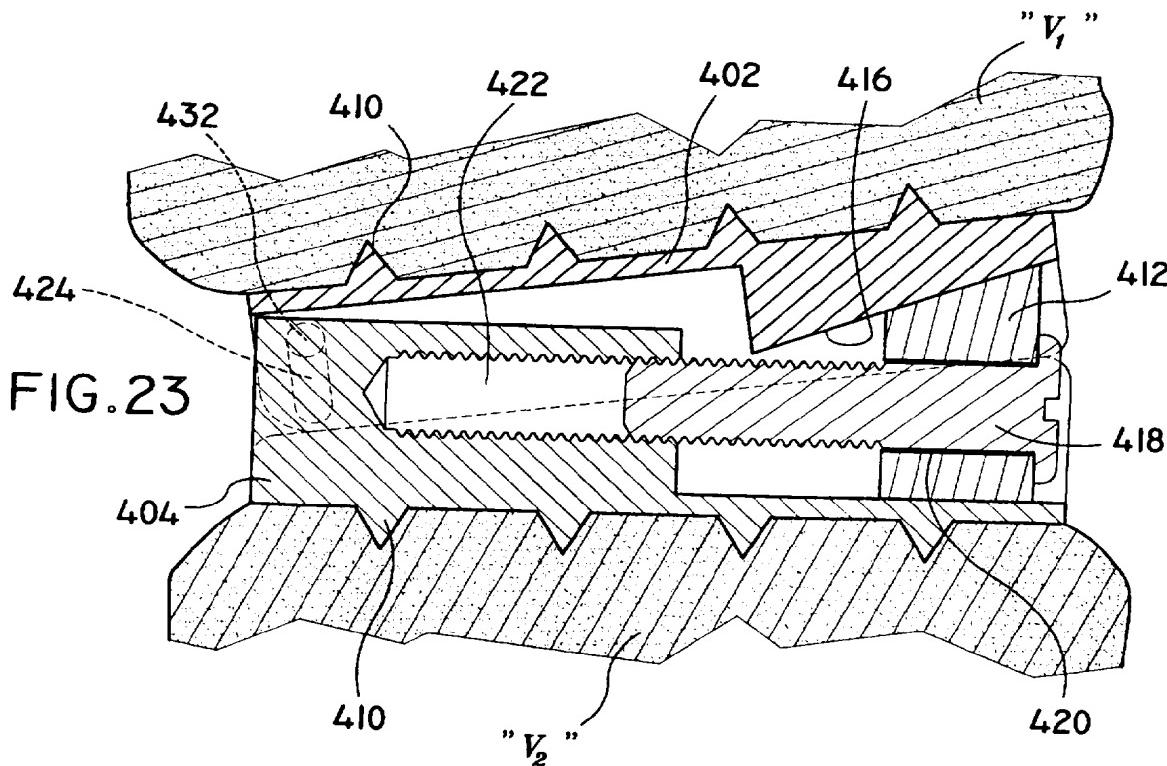
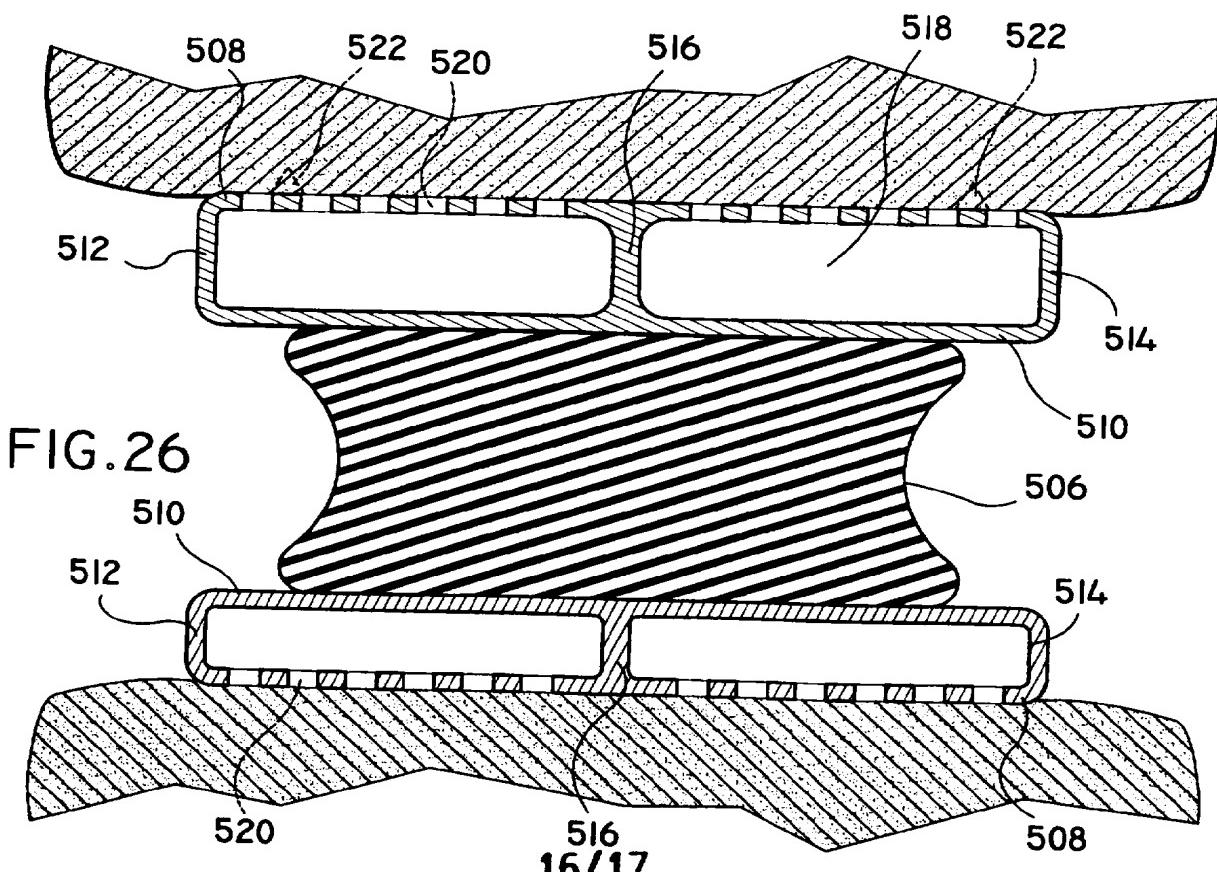
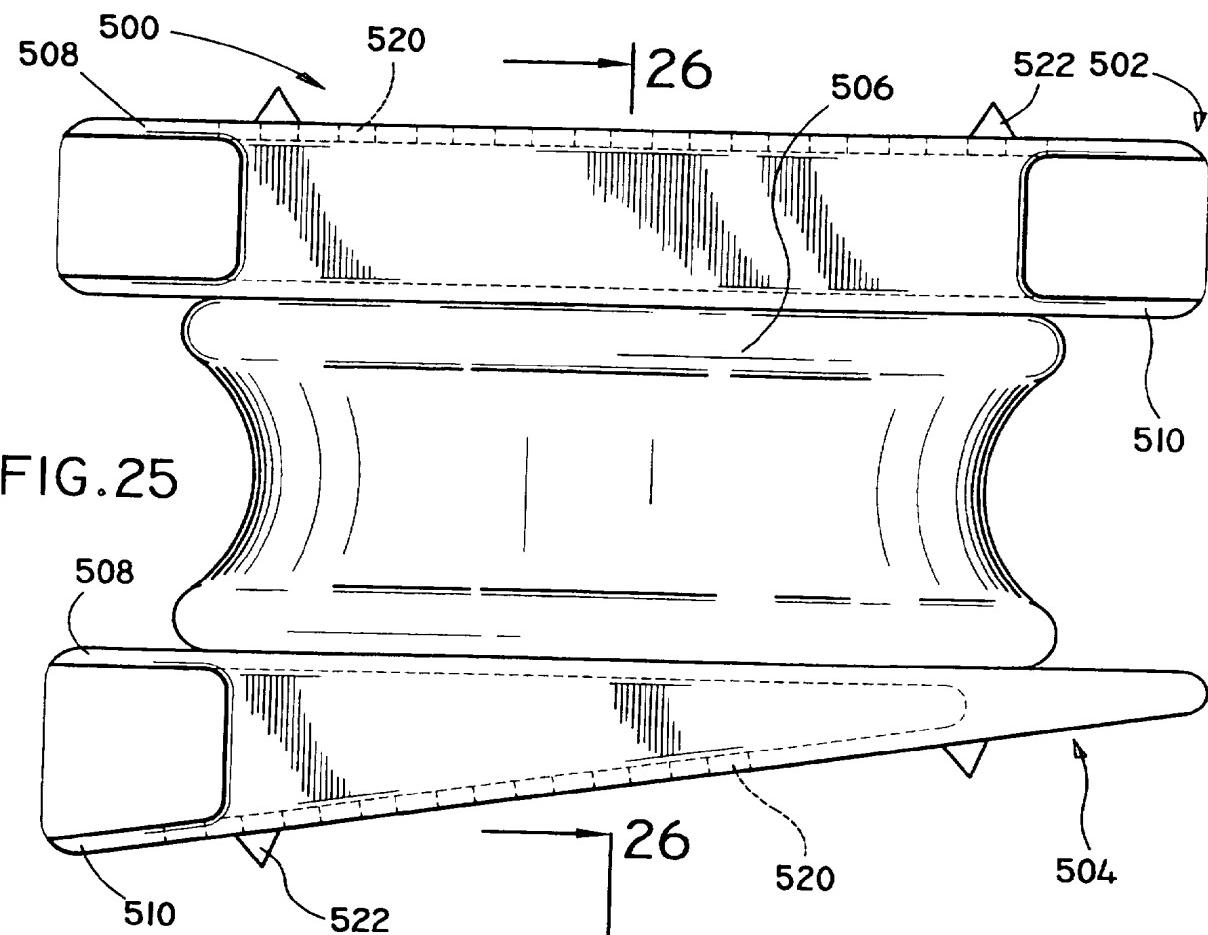


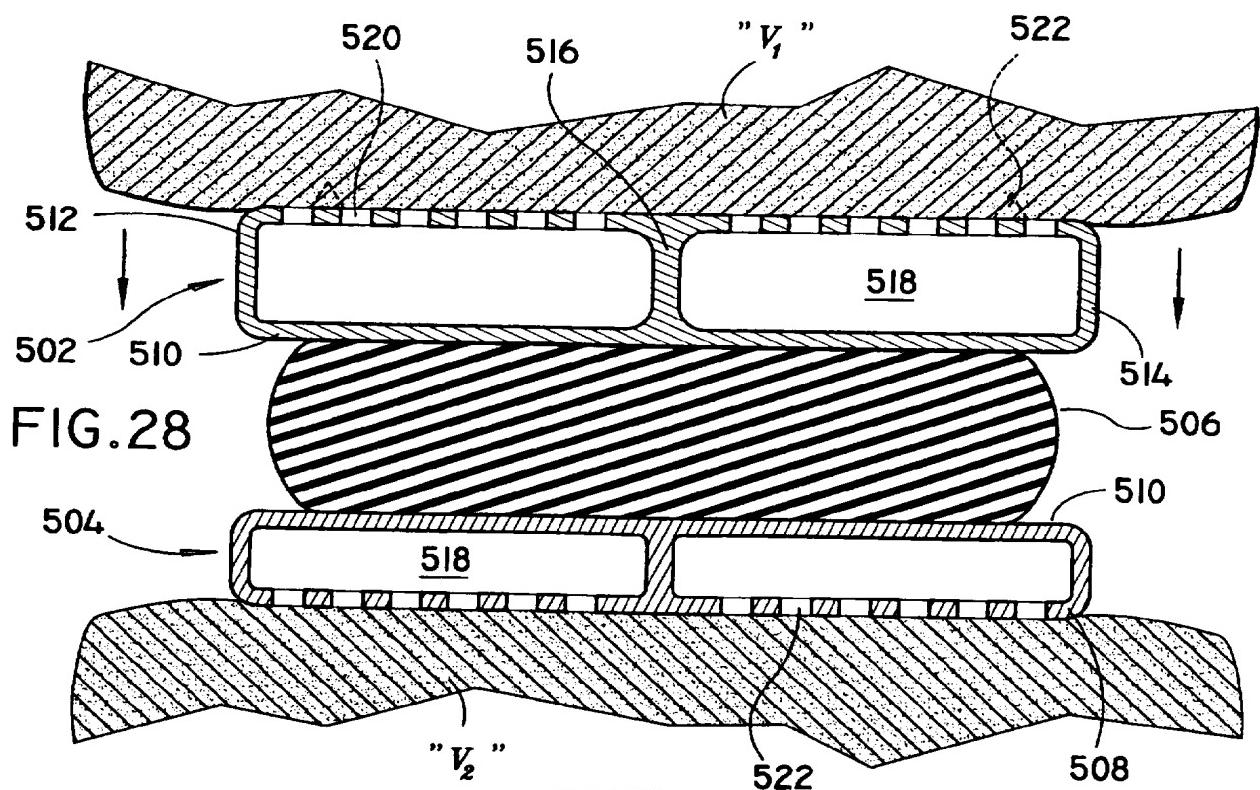
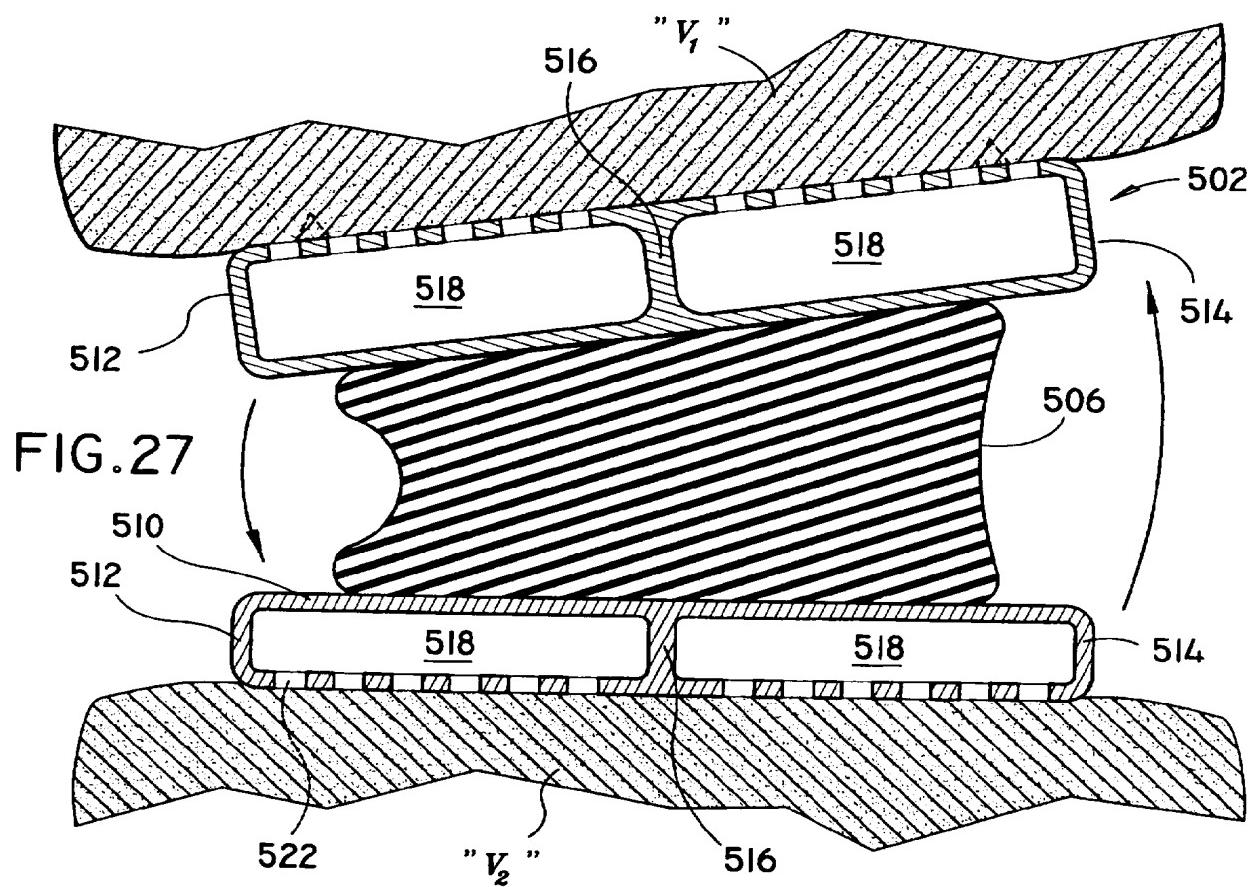
FIG. 21

FIG.22









## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US97/17383

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61F 2/44

US CL : 606/61; 623/17

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 623/17; 606/61

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,360,430 A (LIN) 01 November 1994, Figs. 1 and 3.	9-11
X,P	US 5,665,122 A (KAMBIN) 09 September 1997, Fig. 9.	9, 20, 21
X	EP 94/256681 A (BAUMGARTNER) 27 October 1993, Fig. 1A.	10, 14
X	WO 94/04100 A (MAZDA) 03 March 1994, Fig. 3.	15, 17-19
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Y		16
X,P	US 5,609,635 A (MICHELSON) 11 March 1997, Figs. 1, 8, 30, and 31.	20-22
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Y,P		16

 Further documents are listed in the continuation of Box C.

See patent family annex.

- \* Special categories of cited documents:
- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document published on or after the international filing date
- "L" document which may throw doubt on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed
- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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- "&" document member of the same patent family

Date of the actual completion of the international search

12 DECEMBER 1997

Date of mailing of the international search report

13 JAN 1998

Name and mailing address of the ISA/US  
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JULIAN W. WOO

Telephone No. (703) 308-0421

**INTERNATIONAL SEARCH REPORT**

International application No.

PCT/US97/17383

**C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT**

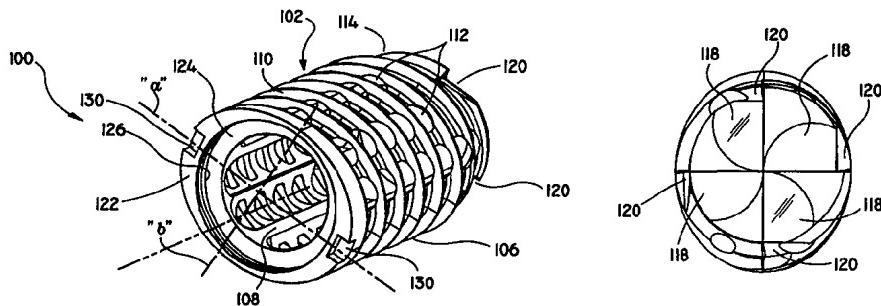
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,071,437 A (STEFFEE) 10 December 1991, Fig. 2.	10
X	US 5,002,576 A (FUHRMANN et al.) 26 March 1991, Fig. 1.	10
A	US 5,258,031 A (SALIB et al.) 02 November 1993, Fig. 3.	15
X	EP 0 610 837 A (NAVARRO et al) 17 August 1994, Ffig.2.	10
A	US 5,507,816 A (BULLIVANT) 16 April 1996, Fig.1A.	15



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## (54) Title: APPARATUS FOR FUSING ADJACENT BONE STRUCTURES



## (57) Abstract

An apparatus for facilitating the fusion of adjacent bone structures (V1, V2) includes an implant member (100) configured for insertion within a space defined between adjacent bone structures (V1, V2). The implant member (100) includes an entry end portion (114) and a trailing end portion (122) and defines a longitudinal axis. The implant member (100) includes at least a longitudinal portion (102) having a generally elliptical cross-sectional dimension with a major cross-sectional dimension (a) greater than a minor cross-sectional dimension (b). A system (200) for drilling a bore in adjacent vertebrae (V1, V2) to facilitate the insertion of a fusion implant (100) includes a surgical retractor (202) having a sleeve member (210) with proximal (212) and distal (214) end portions and defining a longitudinal opening and a drill instrument (204) positionable within the longitudinal opening of the surgical retractor (202). The retractor (202) is configured for insertion at least partially into an intervertebral space between adjacent opposed vertebrae (V1, V2) to distract the adjacent vertebrae (V1, V2) to a desired predetermined distracted position. At least one anchoring member may be associated with the surgical retractor (202) to facilitate mounting thereof to the vertebrae (V1, V2). The drill instrument (204) includes an elongate member (220) having a longitudinal passageway and defining at least one distal cutting surface and a drill member (224) disposed within the elongate member (220) and having a distal drill head. The drill member (224) is rotatably movable within the elongate member (220) and is also longitudinally fixed to the elongate member (220) such that advancement of the drill member (224) within the retractor (202) causes corresponding advancement of the elongate member (220) such that the distal cutting surface of the elongate member (220) and the distal drill head of the drill member (224) cooperate to cut a non-circular, e.g., an elliptical-shaped, bore in the adjacent vertebrae (V1, V2). Preferably, the elongate member (220) of the drill instrument (204) includes first and second diametrically opposed distal cutting surfaces. The cutting surfaces may be arcuately-shaped.

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**APPARATUS FOR FUSING  
ADJACENT BONE STRUCTURES**

**BACKGROUND**

5      **1. Technical Field**

The present disclosure generally relates to a surgical apparatus for fusing adjacent bone structures, and, more particularly, to an apparatus, instrumentation and associated method for fusing adjacent vertebrae.

10     **2. Background of the Related Art**

The fusion of adjacent bone structures is commonly performed to provide for long-term replacement to compensate for degenerative or deteriorated disorders in bone. For example, an intervertebral disc, which is a ligamentous cushion disposed between adjacent vertebrae, may undergo deterioration as a result of injury, disease, tumor or other disorders. The disk shrinks or flattens leading to mechanical instability and painful disc translocations.

15     Conventional procedures for disc surgery include partial or total excision of the injured disc portion, e.g., discectomy, and replacement of the excised disc with biologically acceptable plugs or bone wedges. The plugs are driven between adjacent vertebrae to maintain normal intervertebral spacing and to achieve, over a period of time, bony fusion with the plug and opposed vertebrae. For example, U.S. Patent No. 4,887,020 to Vich discloses a threaded cylindrical bone plug which is screwed into a correspondingly dimensioned cylindrical bore drilled in the intervertebral space. Other bone grafting plugs are disclosed in U.S. Patent No. 4,950,296.

20     More recently, emphasis has been placed on fusing bone structures (i.e., adjoining vertebrae) with prosthetic cage implants. One fusion cage implant is disclosed in commonly assigned U.S. Patent No. 5,026,373 to Ray et al., the contents of which are incorporated herein by reference. The Ray '373 fusion cage

includes a cage having a thread formed as part of its external surface and apertures extending through its wall which communicate with an internal cavity of the cage body. The fusion cage is inserted within a tapped bore or channel formed in the intervertebral space thereby stabilizing the vertebrae and maintaining a pre-defined intervertebral space. Preferably, a pair of fusion cages are implanted within the intervertebral space. The adjacent vertebral bone structures communicate through the apertures and with bone growth inducing substances which are within the internal cavity to unite and eventually form a solid fusion of the adjacent vertebrae.

FIGS. 1-2 illustrate the insertion of a pair of the Ray '373 fusion cages positioned within an intervertebral space.

Both anterior (transabdominal) and posterior surgical approaches are used for interbody fusions of the lumbar spine. Fusions in the cervical area of the spine are also performed using an anterior or a posterior approach. Typically, an implant such as a plug, dowel, prosthesis or cage is inserted into a preformed cavity inside the interbody, interdiscal space. Since it is desirable in these procedures to promote a "bone to bone" bridge, connective tissue and at least a portion of the distal tissue is removed. Preferably, relatively deep cuts are made in the adjacent bones in order to penetrate into the softer, more vascularized cancellous region to facilitate bone growth across the implant.

One of the more critical tasks performed in the insertion of a surgical fusion implant, particularly, in intervertebral spinal fusion, is the formation of the implant receiving cavity or bore within the adjacent vertebrae. More particularly, the drilled bore should be centered with respect to and preferably parallel to the vertebral end plates to ensure removal of equal portions of bone from the adjacent vertebrae throughout the length of the cut and subsequent appropriate seating of the implant relative to the vertebral bodies.

Surgical instruments for spinal fusion implant insertion are known. For example, U.S. Patent No. 5,484,437 to Michelson discloses a method and apparatus incorporating an outer and an inner sleeve arrangement. The outer sleeve has teeth at one end which are driven directly into the posterior surface of the adjacent vertebrae. The inner sleeve is positioned within the outer sleeve and serves to guide instruments such as a drill used to form the implant receiving bore. U.S. Patent Nos.: 5,487,307 to Kuslich et al.; 5,015,247 to Michelson; and 4,878,915 to Brantigan disclose similar arrangements. Other arrangements include the use of guide rods which are placed in pilot holes formed in the vertebral bodies. The guide rods guide a bore forming hollow drill into the intervertebral space.

Although some of the current instrumentation and methods associated therewith for enhancing the placement of spinal fusion implants have been generally effective for their intended purposes, there exists certain limitations with the design of this instrumentation which detract from their usefulness. For example, the arrangement disclosed in the Michelson '437 patent and similar arrangements do not provide for automatic alignment of the outer sleeve to ensure that the bore formed by a drill introduced into the outer sleeve is in optimal alignment for a tapping procedure (if required) and reception of the spinal implant. Rather, such orientation is dependent directly upon the skill of the surgeon. Moreover, the outer sleeve, which is only mounted only at its extreme distal end to the posterior surface of the adjacent vertebrae, is subject to disorientation or dislodgment during insertion and/or removal of the drill and/or tapping instrument. Similarly, the use of guide rods increases the number of steps required to implant the fusion cage and is also subject to possible misalignment.

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U.S. Patent Application Serial No. 08/615,379, filed March 14, 1996, the contents of which are incorporated herein by reference, discloses a method and associated instrumentation to facilitate the introduction of a fusion implant. The instrumentation disclosed in the '379 application ensures optimal alignment of the drilled bore for reception of the fusion implant and, if appropriate, for bore tapping procedures. The instrumentation includes a surgical retractor and a drill. The retractor is configured for distracting adjacent vertebral bodies to facilitate the insertion and application of an implant, for providing a cannula for insertion of auxiliary instruments, e.g., the drill, and for ensuring proper alignment of the instrumentation and accurate insertion of the implant. The instrumentation and method disclosed in the '379 application is well suited for implanting an implant having a general circular cross-sectional portion such as the aforescribed Ray '373 fusion cage.

### SUMMARY

15 Although the Ray '373 fusion cage implant has proven to be effective in stabilizing the vertebrae and promoting vertebral fusion subsequent, for example, discectomy, the present disclosure is directed to further improvements in interbody fusion.

20 Accordingly, an apparatus for facilitating the fusion of adjacent bone structures is disclosed. The apparatus includes an implant member configured for insertion within a space defined between adjacent bone structures and having an entry end portion and a trailing end portion. The implant member includes at least a longitudinal portion having a generally elliptical cross-sectional dimension transverse to a longitudinal axis of the implant member. The elliptical configuration enhances the supporting characteristics of the implant member by increasing surface area contact of the implant member with the bone structures.

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The implant member preferably includes an exterior surface portion having discontinuities to permit bone ingrowth. The external surface portion may also include a threaded portion to facilitate insertion between adjacent bone structures. A hollow interior cavity is defined within the implant member to accommodate bone growth inducing substances to facilitate the fusion process. A plurality of apertures extend through the external surface portion in communication with the interior cavity wall portion, to thereby permit bone ingrowth to facilitate fusion of the adjacent bone structure.

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The entry end portion of the implant member defines a generally circular cross-sectional dimension transverse to the longitudinal axis to facilitate positioning between the adjacent bone structures. The entry end portion includes closed entry end surface.

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At least one flute may be formed on the exterior surface portion to capture bone material removed during insertion of the implant within the bone structures. The one flute is disposed adjacent the entry end portion and is formed in the threaded portion. Preferably, the one flute extends to the closed entry end surface.

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An apparatus for facilitating fusion of adjacent vertebrae is also disclosed. The apparatus includes an implant member configured and dimensioned for insertion within an intervertebral space defined between adjacent vertebrae. The implant member includes at least a longitudinal section having a transverse cross-sectional dimension defining a generally elliptical configuration. The implant member includes an internal cavity for accommodating bone growth inducing substances and a plurality of apertures extending through an external wall portion thereof in communication with the internal cavity. An external threaded portion is formed on the implant member for facilitating insertion within the intervertebral space.

A system and associated method to facilitate insertion of the fusion implants is also disclosed. In a preferred embodiment, a system for drilling a bore in adjacent vertebrae to facilitate the insertion of a fusion implant includes a surgical retractor including a sleeve member with proximal and distal end portions and defining a longitudinal opening and a drill instrument positionable within the longitudinal opening of the surgical retractor. The distal end portion of the retractor is configured for insertion at least partially into an intervertebral space between adjacent opposed vertebrae to distract the adjacent vertebrae to a desired predetermined distracted position.

Preferably, the drill instrument includes an elongate member having a longitudinal passageway and defining at least one distal cutting surface and a drill member disposed within the elongate member and having a distal drill head. The drill member is rotatably movable within the elongate member and is also longitudinally fixed to the elongate member such that advancement of the drill member within the retractor causes corresponding advancement of the elongate member such that the distal cutting surface of the elongate member and the distal drill head of the drill member cooperate to cut a bore, e.g., an elliptical-shaped bore, in the adjacent vertebrae. Preferably, the elongate member of the drill instrument includes first and second diametrically opposed distal cutting surfaces. The cutting surfaces may be arcuately-shaped.

Preferably, the distal end portion of the retractor includes two spaced apart retractor arms having first and second support surfaces which respectively engage and distract upper and lower vertebrae. At least one anchoring member may be associated with the surgical retractor to facilitate mounting of the retractor to the vertebrae.

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The system may further include alignment means for aligning and maintaining the elongate member of the drill instrument at a predetermined angular orientation within the sleeve member of the surgical retractor. The preferred alignment means is adapted to angularly orient the first and second distal cutting surfaces in general alignment within respective retractor arms of the surgical retractor. The alignment means may include at least one groove defined in the sleeve member of the surgical retractor, the one groove dimensioned to accommodate a corresponding spline of the elongate member.

The present disclosure is also directed to a system for drilling a bore in adjacent vertebrae to facilitate the insertion of a fusion implant comprising a surgical retractor including a sleeve member having proximal and distal end portions and defining a longitudinal opening, with the distal end portion configured for insertion at least partially into an intervertebral space between adjacent opposed vertebrae to distract the adjacent vertebrae and the sleeve member including an internal threaded portion. A drill instrument is positionable within the longitudinal opening of the surgical retractor, and includes a drill member having a distal cutting head and an external threaded portion engageable with the internal threaded portion of the retractor whereby rotation of the drill instrument causes distal translation of the drill instrument relative to the surgical retractor.

A method for performing a surgical procedure with the system is also disclosed. The method includes the steps of providing a surgical retractor including an elongate member defining a longitudinal opening and having two spaced apart retractor arms with first and second supporting surfaces at its distal end, inserting the retractor arms of the retractor within the intervertebral space whereby the first and second supporting surfaces of each retractor arm respectively engage and distract the adjacent opposed vertebrae, mounting the surgical retractor to the adjacent vertebrae by securing an anchor member associated with the

surgical retractor to the adjacent vertebrae and performing the surgical procedure adjacent the distracted vertebrae by, e.g., introducing surgical instrumentation within the opening of the surgical retractor.

A method for fusing adjacent vertebral bodies with the system is also disclosed. The method includes the steps of accessing the intervertebral disc space, providing a retractor including a retractor sleeve having opposed retractor arms extending in a general longitudinal direction, positioning the retractor arms within the intervertebral disc space whereby first and second supporting surfaces of each arm contact opposed vertebra bodies, introducing a drill instrument into the retractor sleeve and advancing the drill instrument within the sleeve to the disc space wherein the drill instrument includes an elongate member having a longitudinal passageway and defining at least one distal cutting surface and a drill member rotatably mounted within the elongate member and having a distal cutting head, actuating the drill instrument such that the distal cutting head of the drill member and the distal cutting surface of the elongate member are advanced into the adjacent vertebrae to cooperate and cut a bore in the adjacent vertebra, removing the drill instrument from the sleeve, and introducing a fusion implant into the bore. Preferably an elliptical bore is formed and a fusion implant having an elliptical cross-sectional dimension is inserted into the bore.

#### **BRIEF DESCRIPTION OF THE DRAWINGS**

Preferred embodiment(s) of the present disclosure are described herein with reference to the drawings wherein:

FIG. 1 is a view illustrating a portion of the vertebral column of a patient;

FIG. 2 is a view taken along line 2-2 of FIG. 1 illustrating a pair of prior art fusion implants positioned within the intervertebral space for fusion of adjacent vertebrae;

FIGS. 3-4 are front and rear perspective views of the fusion implant in accordance with the principles of the present disclosure;

FIG. 5 is a perspective view of the fusion implant of FIGS. 3-4 illustrating the implant body and detachable end cap;

FIG. 6 is a side plan view of the implant body;

FIG. 7A is an axial view taken along line 7A-7A of FIG. 6 illustrating the entry end portion of the implant body;

FIG. 7B is an axial view taken along lines 7B-7B of FIG. 6 illustrating the trailing end portion of the fusion implant;

FIG. 8 is a side cross-sectional view of the implant body and mounted end cap taken along line 8-8 of FIG. 7B;

FIG. 9 is a top cross-sectional view of the implant body and mounted end cap taken along line 9-9 of FIG. 7B;

FIG. 10A is a cross-sectional view taken along line 10A-10A of FIG. 9 illustrating a section through the major diameter of the thread;

FIG. 10B is a cross-sectional view taken along line 10B-10B of FIG. 9 illustrating a section through the minor diameter of the thread;

FIG. 11 is a cross-sectional view taken along line 11-11 of FIG. 9 illustrating the circular configuration of the entry end portion of the implant body;

FIG. 12 is a perspective view of an instrumentation kit utilized for inserting the fusion implant within the intervertebral space, including a surgical retractor, a surgical drill, an implant insertion instrument and a T-shaped handle;

FIG. 13 is a view illustrating the lateral insertion of the surgical retractor within the intervertebral space;

FIG. 14 is a view taken along line 14-14 of FIG. 13 further illustrating positioning of the retractor within the intervertebral space and engagement of the retractor with the vertebral end faces of the adjacent vertebrae;

5 FIG. 15 is a view similar to the view of FIG. 14 illustrating insertion of a drilling instrument into the retractor to drill a bore within the adjacent vertebrae;

FIG. 16 is a side plan view illustrating the insertion instrument with the fusion implant mounted to the insertion instrument;

10 FIG. 16A is a cross-sectional view of the distal end of the insertion instrument and the fusion implant illustrating mounting of the end cap to the implant body;

FIG. 17 is a view similar to the view of FIG. 15 illustrating insertion of the insertion instrument and mounted implant through the retractor;

15 FIGS. 18-20 are enlarged views illustrating positioning of the fusion implant within the preformed bore;

FIG. 21 is a view illustrating the fusion implant mounted within the intervertebral space;

FIG. 22 is a sectional view further illustrating the fusion implant mounted within the intervertebral space;

20 FIG. 23 is a view illustrating a different sized fusion implant mounted within the vertebral space;

FIG. 24 is a perspective view of an alternate system for inserting the implant of FIGS. 3-11 including a surgical retractor utilized in distracting adjacent bony structures and a surgical drilling instrument utilized in drilling a bore within the adjacent bony structure in accordance with the principles of the present disclosure;

FIG. 24A is a perspective view of an insertion instrument and detached T-handle utilized in inserting an implant within the adjacent bony structures;

5 FIG. 25 is a perspective view with parts separated of the surgical retractor of FIG. 24;

FIG. 26 is a side view in cross-section of the surgical retractor of FIG. 25;

10 FIG. 26A is an isolated view of the anchoring member being retained within the retractor;

FIG. 27 is an axial view of the surgical retractor;

FIG. 28 is a side plan view of the drilling instrument;

15 FIG. 29 is an isolated view in cross-section illustrating the mounting of the drill shaft and drill bit and the mounting of the extension sleeve and the drill shaft;

FIG. 30 is an axial view of the drilling instrument;

FIG. 31 is a view of a portion of the vertebral column;

20 FIG. 32 is a sectional view of the vertebral column taking along the lines 31-31 of FIG. 31 illustrating insertion of the surgical retractor within the intervertebral space;

FIG. 33 is a cross-sectional view further illustrating the surgical retractor inserted within the intervertebral space;

25 FIG. 34 is a view similar to the view of FIG. 33 illustrating mounting of the anchoring screws into the vertebral column;

FIG. 35 is a view similar to the view of FIG. 34 illustrating insertion of the drilling instrument into the surgical retractor;

FIG. 36 is a view similar to the view of FIG. 35 illustrating advancement of the drilling instrument to drill a bore within adjacent vertebrae;

FIG. 36A is a cross-sectional view taken along the lines 36A-36A of FIG. 36;

5 FIG. 37 is a view similar to the view of FIG. 36 illustrating insertion of the insertion instrument and mounted fusion implant into the surgical retractor to insert the implant;

10 FIG. 38 is a sectional view illustrating the fusion implant mounted within the intervertebral space; and

15 FIG. 39 is a view further illustrating the fusion implant mounted within the intervertebral space.

#### **DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS**

The preferred embodiment of the apparatus and method disclosed herein are discussed in terms of orthopedic spinal fusion procedures and instrumentation. It is envisioned, however, that the disclosure is applicable to a wide variety of procedures including, but, not limited to ligament repair, joint repair or replacement, non-union fractures, facial reconstruction and spinal stabilization. In addition, it is believed that the present method and instrumentation finds application in both open and minimally invasive procedures including endoscopic and arthroscopic procedures wherein access to the surgical site is achieved through a cannula or small incision.

20 The following discussion includes a description of the fusion implant utilized in performing a spinal fusion followed by a description of the preferred method for spinal fusion in accordance with the present disclosure.

25 In the discussion which follows, the term "proximal", as is traditional, will refer to the portion of the structure which is closer to the operator, while the term "distal" will refer to the portion which is further from the operator.

**Fusion Implant**

Referring now to the drawings in which like reference numerals identify similar or identical elements throughout the several views, FIGS. 3-5 illustrate in perspective the fusion implant of the present disclosure. Fusion implant 100 is contemplated to be a self-tapping implant, i.e., the implant is intended to be inserted within a preformed bore in adjacent bone structures, e.g., adjacent vertebrae, without necessitating tapping of an internal thread within the bone structures prior to insertion and is preferably configured for lumbar vertebrae. Fusion implant 100 includes elongated implant body 102 and end cap 104 which is mountable to the implant body 102. Implant body 102 is preferably fabricated from a suitable biocompatible rigid material such as titanium and/or alloys of titanium, stainless steel, ceramic materials or rigid polymeric materials. Implant body 102 is preferably sufficient in strength to at least partially replace the supporting function of an intervertebral disc, i.e., to maintain adjacent vertebrae in desired spaced relation, during healing and fusion, and is strategically dimensioned to span the intervertebral space such that only one implant (as opposed to two as is conventional) is required for insertion. The implant 100 is preferably provided in various lengths such as about 24 mm, 26 mm and 28 mm for example.

As best depicted in FIGS. 5-7B, implant body 102 is generally elliptical in configuration defining a major axis "a" greater than a minor axis "b" (FIG. 5). This configuration provides a greater surface area of the implant so as to facilitate contacting engagement and support of the implant with the adjacent vertebrae. In particular, as discussed in greater detail hereinbelow, in the inserted position of the fusion implant 100, the major axis "a" is in general parallel relation with the vertebral end faces of the adjacent vertebrae, thus, positioning the major arc or outer surface of implant body 102 in contact with the vertebral end faces. The oval or elliptical configuration and dimensions enable one implant to be

utilized instead of two implants of the prior art. The elliptical configuration of implant body 102 also minimizes any tendency of the inserted implant 100 from backing out of the preformed bore. Implant body 102 includes an outer wall 106 which enclose an inner cavity 108 defined within the interior of the implant body 102. Inner cavity 108 accommodates bone growth inducing substances which facilitate the fusion process.

In a preferred embodiment, the diameter of the implant 102 along its major axis preferably ranges from about 16 mm to about 20 mm, and preferably is about 19 mm. The diameter along the minor axis preferably ranges from about 14 mm to about 17 mm, and preferably is about 16 mm. Other dimensions are also contemplated.

With reference to FIGS. 8-10B, in conjunction with FIG. 5, outer wall 106 has an external threaded configuration formed as part of its exterior surface. External threaded configuration including a continuous helical thread 110 which assists in advancing implant body 102 into a preformed channel provided in the adjacent vertebrae. Thread 110 as shown preferably has an angled face on the posterior side and a sharp end toward the anterior side to prevent expulsion to the anterior side. Thread 110 is preferably a self-tapping cutting thread, i.e., the threads are capable of deburring bone material during advancement into the performed channel. Alternatively, a thread can be tapped in the bone prior to insertion of the implant.

A plurality of apertures 112 extend through outer wall 106 of implant body 102. Apertures 112 are preferably formed by broaching grooves in the internal surface of the internal cavity 108. The effect of such broaching is to remove material from the valleys between the threads 110, thus defining the apertures 112. The advantages of such an arrangement are disclosed in U.S. Patent No. 4,961,740, the contents of which are incorporated herein by reference,

and include immediate bone to bone contact between the vertebral bodies or bone structures and the bone inducing substances packed within the internal cavity 108 of the implant body 102. Apertures 112 are preferably substantially the same in dimension although it is envisioned that the dimensions of the apertures may vary to provide for more or less bone to bone contact as desired.

As best depicted in FIGS. 10A-10B, apertures 112 are clustered about a transverse axis or minor axis "b", both at the upper and lower end of the axis. Consequently, apertures 112 come into contact with the upper and lower vertebral bone structures to encourage bone growth through implant body 102 from the vertebral bone structures. The lateral sections of implant body 102 formed along the major axis "a" do not have apertures in order to prevent growth of disk material which might interfere with the bone fusing process.

With reference now to FIGS. 6-7A and 11, the entry or leading end portion (distal) 114 of implant body 102 is preferably rounded, i.e., generally circular in cross-section as best depicted in FIG. 11 and defines a closed rounded entry end surface 116. This facilitates insertion. End surface 116 includes a plurality of flutes or relief grooves 118 formed in its surface. (four are shown). Flutes 118 assist in insertion of fusion implant 100 within the intervertebral space by capturing bone material deburred during the self-tapping process. In a preferred embodiment, flutes 118 meet at a central point of the longitudinal axis on the entry end of surface 116 and extend proximally to at least the first turn of the thread on implant body 102. The flute portions formed on thread 110 are defined by the sections 120 which are removed from the thread. (See also FIG. 5.) This arrangement permits adequate relief for purposes of self tapping of implant 100 in the intervertebral space. It is also envisioned that the flutes may run deeper and extend from the leading end 114 completely to the end cap 104, or, to a position intermediate the end cap 104 and the leading end 114.

With reference now to FIG. 5 and FIG. 7B, the trailing end portion 122 of implant body 102 has a generally annular recess 124 which receives end cap 104. An internal thread 126 is disposed adjacent annular recess 124 and cooperates with external thread 128 on the periphery of end cap 104 to mount the end cap to implant body 102. Trailing end portion 122 also includes a pair of diametrically opposed notches 130. Notches 130 are dimensioned to be engaged by corresponding structure of an insertion apparatus utilized in inserting the implant within the vertebral column. End cap 104 includes a central threaded aperture 132 which threadably engages corresponding structure of the insertion apparatus to assist in the mounting of the cap 104 on implant body 102.

#### Instrumentation Kit

Referring now to FIG. 12, there is illustrated one preferred instrumentation kit for inserting spinal implant 100 within the intervertebral space. The instrumentation kit 200 includes surgical retractor 202, drill instrument 204 and insertion instrument 206. A T-shaped handle 208 is also provided in kit 200, and is utilized to actuate drill instrument 204 and insertion instrument 206.

Surgical retractor 202 is disclosed in commonly assigned U.S. patent Application Serial No. 08/615,379, filed March 14, 1996, the contents of which are incorporated herein by reference. Retractor 202 is configured for distracting adjacent vertebral bodies to facilitate the insertion and application of an implant, for providing a cannula for insertion of the instruments, and for ensuring proper alignment of the instrumentation and accurate insertion of the implant. Retractor 202 includes sleeve 210 with an enlarged head 212 at the proximal end of the sleeve 210. Sleeve 210 includes first and second diametrically opposed retractor arms 214 having first and second parallel vertebrae supporting surfaces 216, 218.

Drill instrument 204 is also disclosed in the '379 application. Drill instrument 204 includes drill shaft 220, extension shaft 222 and drill bit 224 mounted at the distal end of the drill shaft. T-handle 208 is mountable to a proximal mounting section of the drill instrument 204. Extension shaft 222 has first and second collars 226, 228 which cooperate to control the depth of penetration of drill shaft 220 into the adjacent vertebrae.

Insertion instrument 206 is disclosed in commonly assigned U.S. patent Application Serial No. 08/616,120, filed March 14, 1996, the contents of which are also incorporated herein by reference. Insertion instrument 206 includes implant engaging structure 230 at its distal end which is correspondingly configured to mount and release implant 100 as will be discussed herein below. A pair of control wheels 232, 234 serve to control actuation of insertion instrument 206 thereby controlling mounting and releasing of the implant within the intervertebral space.

#### 15 Insertion of Fusion Implant With Instrumentation Kit

The insertion of the fusion implant 100 with the instrumentation kit 200 into an intervertebral space defined between adjacent lumbar vertebrae will now be described. The subsequent description will be particularly discussed in conjunction with an open antero-lateral approach for spinal fusion implant insertion. However, it is to be appreciated that other approaches, e.g., posterior, direct anterior, etc... could be utilized. Laparoscopic approaches are also envisioned.

With respect now to FIG. 13, the intervertebral space "i" is accessed utilizing appropriate retractors to expose the anterior vertebral surface. Thereafter, retractor 202 is inserted within the intervertebral space "i" from an antero-lateral or oblique approach with relation to the vertebral columns 216, 218 as depicted in

FIG. 13. Such approach provides advantages with regard to avoiding interference by the great vessels "g" (FIG. 13) and limiting penetration of the anterior longitudinal ligament "l". The retractor may be inserted by placing an impactor cap at the proximal end and impacting the retractor into the intervertebral space.

5 FIG. 14 depicts retractor 202 positioned within the intervertebral space "i" with the retractor arms 214 arranged such that the first and second supporting surfaces 216,218 of each retractor arm 214 respectively engage the opposed vertebral bodies "V<sub>1</sub>, V<sub>2</sub>". Upon insertion of retractor arms 214, the vertebral bodies "V<sub>1</sub>, V<sub>2</sub>" are distracted whereby the retractor arms become firmly 10 lodged within the intervertebral space "i".

15 Referring now to FIG. 15, the drilling instrument 204 is now utilized to prepare the disc space and vertebral end plates for insertion of the fusion implant. The cutting depth of drilling instrument 204 is adjusted as desired (i.e., to correspond to the length of the fusion implant) by adjusting collars 226, 228. With the T-handle 208 mounted to drilling instrument 204, the instrument is introduced into retractor 202 and advanced to contact the anterior surface of the vertebral bodies "V<sub>1</sub> V<sub>2</sub>". Drilling instrument 204 is advanced into the 20 intervertebral space "i" by rotating T-handle 208 to shear the soft tissue and cut the bone of the adjacent vertebrae "V<sub>1</sub> V<sub>2</sub>" thereby forming a bore which extends into the adjacent vertebrae "V<sub>1</sub>, V<sub>2</sub>".

Subsequent to the drilling process, fusion implant 100 is packed with bone growth inducing substances "b" as in conventional in the art and end cap is threaded into recess 124 of implant body 102 either by hand, with a socket wrench-type instrument or with insertion instrument 206 as depicted in FIG. 16A. 25 In particular, as shown in FIG. 16A, end cap 104 may be threaded onto mounting screw 232 of insertion instrument 206 and then threaded into recess 124 of implant body 102 via rotation of wheel 232. The fusion implant 100 is then mounted on.

insertion instrument 206 by positioning distal tabs 234 of insertion instrument 206 within correspondingly dimensional recesses 128 of end cap 104 (FIG. 5). FIG. 16 illustrates fusion implant 100 mounted to insertion instrument 206. Further details of the mounting of implant 100 to insertion instrument 206 may be ascertained by reference to the '120 application.

Referring now to FIG. 17, insertion instrument 206 and mounted implant 100 is introduced within retractor 204 and advanced to a position adjacent the vertebral bodies "V<sub>1</sub>, V<sub>2</sub>". Thereafter, insertion instrument 206 is rotated via T-shaped handle 202 which is mounted to the instrument 206 to thereby cause corresponding rotation of fusion implant 100. As fusion implant 100 rotates, the thread 110 of the implant body 102 bites into the vertebral bodies "V<sub>1</sub>, V<sub>2</sub>". Continued rotation of insertion tool 206 causes implant to move through the position shown in FIG. 18 to the position shown in FIG. 19 to be self-tapped within the preformed bore. Implant 100 is released from its mounting to insertion tool 206 and the instrument 206 and retractor 204 are removed from the disc area.

FIGS. 20-22 depict fusion implant 100 inserted within the intervertebral space "i". As shown, fusion implant 100 forms a strut across the intervertebral space "i" to maintain the adjacent vertebrae "V<sub>1</sub>, V<sub>2</sub>" in appropriate spaced relation during the fusion process. The implant is thus preferably inserted at an angle of between about 15 degrees and about 45 degrees, and more preferably at about 30 degrees to the longitudinal axis of the spine and to the right of the great vessels as view anteriorly. As also shown, in the inserted position of implant 100, the major axis "a" is in general parallel relation to the vertebral end plates thus presenting the greater arc or surface area of implant body 102 to contact and support the adjacent vertebrae. Over a period of time, the adjacent vertebral tissue communicates through apertures 112 with the bone growth inducing substances "b" within the interior cavity 108 of implant to form a solid

fusion. Thus only one implant is required as opposed to two implants of the prior art as shown in Fig. 2. Implantation of the implants M1, M2 of Fig. 2 require greater manipulation due to the presence of the great vessels "g" and require increased penetration of the anterior longitudinal ligament "l".

5 FIG. 23 by way of example illustrates a different sized fusion implant 100' positioned within the intervertebral space. This cage fills a larger portion of the disc space.

#### Alternate Instrumentation Kit

10 FIG. 24 illustrates, in perspective, an alternate surgical system or kit particularly contemplated for facilitating the insertion of the fusion implant of FIGS. 3-11 within the intervertebral space defined between adjacent vertebrae. System 500 generally includes two surgical instruments, namely retractor 1000 and drilling instrument 2000 which is positionable within the retractor 1000.

15 With reference now to FIGS. 25-27, in conjunction with FIG. 24, retractor 1000 includes elongated retractor sleeve 1020 defining a longitudinal axis "a" and having longitudinal opening or passageway 1040 extending therethrough. Retractor sleeve 1020 includes first and second diametrically opposed rails 1060 extending longitudinally along the outer surface of the retractor sleeve 1020. Each rail 1060 has a longitudinal opening 1080. An anchoring member 1100 is disposed 20 within opening 1080 of each rail 1060. Anchoring member 1100 is intended to positively fix retractor 1000 to the bony structures, e.g., adjacent vertebrae. In the preferred embodiment, anchoring member 1100 is in the form of an elongated screw as shown and includes a distal screw thread 1120 which is advantageously configured to penetrate and become mounted within bony tissue. The proximal 25 end of anchoring member 1100 includes structure, e.g., a Phillips head 1140, to be engaged by a driving member, e.g., a Phillips head screw driver or the like, to

rotate and advance the anchoring member 1100 in a conventional manner. As depicted in FIG. 26, each anchoring member 1100 is biased proximally by coil spring 1160 whereby distal screw thread 1120 is disposed within opening 1060 of rail 1060 in the unadvanced position of the anchoring member 1100. Anchoring member 1100 is retained within each rail 1060 by lip 1180 extending within opening 1080 of each rail 1060 and engaging the proximal edge of the anchoring member (FIG. 26A), thereby preventing the anchoring member 1100 from exiting the proximal end of retractor sleeve 1020.

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Anchoring member 1100 thus constitutes "anchoring means" to positively mount surgical retractor 1000 to the adjacent vertebrae. Other forms of anchoring means are envisioned as well such as, but, not limited to, fasteners, staples, clips etc... which may be driven from the proximal location of retractor sleeve 1020. Additional forms of "anchoring means" may include suture ties, bands, clamps, etc. ....

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With reference again to FIGS. 25-27, retractor 1000 includes first and second diametrically opposed retractor arms 1200 extending from the distal end of retractor sleeve 1020. Each retractor arm 1200 has first and second supporting surfaces 1200a, 1200b (FIG. 26) extending in general parallel relation to each other and preferably to the longitudinal axis of retractor sleeve 1020. The height "h" of each arm (i.e., the distance between supporting surfaces 1200a, 1200b) corresponds to the height of the space between adjacent bony structures to be distracted. For example, in spinal implant application, the height "h" of each arm can range from about 0.28 inches to about 0.35 inches. Each arm 1200 further includes tapered end portions 1220 defining a general V-shaped configuration. End portions 1220 facilitate insertion of retractor arms 1200 within the surgical site, e.g., within the intervertebral space.

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The proximal end of retractor sleeve 1020 defines an inner threaded bore 1240. Threaded bore 1240 assists in causing translation of the surgical drilling instrument 2000 through retractor sleeve 1020 as will be discussed. Retractor 1000 further includes first and second inner longitudinal recesses 1260 which each extend from the proximal end of retractor sleeve 1020 to an intermediate point of retractor arms 1200. First and second longitudinal recesses 1260 function in maintaining proper alignment of the surgical drilling instrument 2000 inserted within retractor 1000 as will be appreciated from the description provided hereinbelow.

Referring now to FIGS. 28-30, in conjunction with FIG. 24, the surgical drilling instrument 2000 of the system 100 will be discussed. Drilling instrument 2000 is advantageously configured to form an elliptical-shaped bore in the adjacent vertebrae to accommodate the elliptical implant. Clearly, the drill can be configured to form other shaped bores. Drilling instrument 2000 includes drill shaft 2020, drill bit 2040 connected to and extending distally from the drill shaft 2020 and extension sleeve 2060 mounted to the distal end of the drill shaft 2020. In a preferred arrangement, depicted in detail in FIG. 29, drill shaft 2020 includes an internal threaded recess 2080 which threadably engages external threaded portion 2100 of drill bit 2040 to connect the components. With this arrangement, rotational movement of the drill shaft 2020 causes corresponding rotational movement of the drill bit 2040. Drill bit 2040 defines distal cutting edges 2040a which form a generally circular bore in the bone structures.

Extension sleeve 2060 is mounted to drill shaft 2020 to permit relative rotational movement of the two components. In a preferred arrangement, drill shaft 2020 includes a circumferential mounting recess 2120 which receives correspondingly dimensioned circumferential mounting lip 2140 of extension sleeve 2060 in sliding manner to permit rotational movement of the drill shaft 2020 and,

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thus, rotational movement of the drill bit 2040 within the extension sleeve 2060. Extension sleeve 2060 further defines first and second axial splines 2160 disposed on the outer surface of the extension sleeve 2060 in diametrical arrangement. Axial splines 2160 are received within longitudinal recesses 1260 (FIG. 25) within the interior of the sleeve 2060 to rotationally fix the extension sleeve 2060 within retractor 1000.

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Extension sleeve 2060 further defines diametrically opposed cutting arms 2180 at its distal end. Cutting arms 2180 define distal cutting surfaces 2180a which are advantageously dimensioned to cut or shear bony tissue upon advancement of the drill instrument 2000 into the tissue. Cutting surfaces 2180a are preferably arcuate in cross-section as best depicted in FIG. 30. As will be better appreciated hereinbelow, cutting surfaces 2180a in combination with drill bit 2020 form a general elliptical bore in the bony tissue. In particular, drill bit 2020 forms through a drilling action a circular hole while cutting surfaces 2180a cut by a chiseling, shearing action diametrically opposed arcuate sections adjacent the circular bore thereby defining an elliptical configuration of the formed bore in the tissue section.

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Referring still to FIGS. 28-30, drill shaft 2020 further includes stationary collar 2200 and first and second movable collars 2220, 2240 adjacent the stationary collar 2200. Moveable collars 2220, 2240 are threadably mounted on threaded portion 2260 and are each moveable on the threaded portion 2260 between a proximalmost position adjacent stationery collar 2200 and a distalmost portion remote from the collar 2200. First collar 2220 serves as a positioning collar, i.e., by adjusting the positioning of first collar 2220 on threaded portion 2260, the depth of penetration of drill shaft 2020 into the bony structures may be adjusted. Second collar 2240 serves as a locking collar to selectively lock the first collar 2220 at a predetermined location on threaded portion 2260.

Drill shaft 2020 further includes an intermediate external threaded portion 2280 disposed at about the midpoint of the drill shaft 2020 to assist in translation of the drill shaft 2020 within the retractor 1000. More particularly, threaded portion 2280 cooperatively threadably engages internal threaded bore 1240 disposed within retractor sleeve 1020. Accordingly, rotation of the drill shaft 2020 causes the drill shaft 2020 to translate longitudinally within the retractor 1000. The proximal end of drill shaft 2020 includes mounting structure 2300, e.g., a hexagonal-shaped head, which cooperates with corresponding structure of a T-shaped handle (to be discussed) to assist in operating the drilling instrument.

FIG. 24A illustrates one type of insertion instrument 4000 utilized to insert the implant 100 within the intervertebral space and a T-shaped handle 5000 utilized to actuate the insertion instrument 4000 and the drilling instrument 2000. Insertion instrument 4000 is disclosed in commonly assigned U.S. patent Application Serial No. 08/616,120, filed March 14, 1996, the contents of which are incorporated herein by reference. Insertion instrument 4000 includes implant engaging structure 4020 at its distal end which is correspondingly configured to mount and release implant 100 as will be discussed hereinbelow. A pair of control wheels 4040, 4060 serve to control actuation of insertion instrument 4000 thereby controlling mounting and releasing of the implant within the intervertebral space. T-shaped handle 5000 is mountable to the proximal end of drilling instrument 2000 and to the proximal end of the insertion instrument 4000. Handle 5000 includes hex-head recess 5020. Further details of this instrument 4000 and handle 5000 may be ascertained by reference to the '120 application.

### Use of the System For Insertion of the Fusion Implant

The use of the system 500 for the insertion of the fusion implant 100 into an intervertebral space defined between adjacent lumbar vertebrae will now be described. The subsequent description will be particularly discussed in conjunction with an open antero-lateral approach for spinal fusion implant insertion. However, it is to be appreciated that other approaches, e.g., posterior, direct anterior, etc... could be utilized. Laparoscopic approaches are also envisioned.

With respect now to FIGS. 31-32, the desired intervertebral space "i" between adjacent vertebrae "v<sub>1</sub>, v<sub>2</sub>" is accessed utilizing appropriate retractors to expose the anterior vertebral surface. Thereafter, retractor 1000 is inserted within the intervertebral space "i" from an antero-lateral or oblique approach with relation to the vertebral columns "v<sub>1</sub>, v<sub>2</sub>" as depicted in FIG. 32. Such approach provides advantages with regard to avoiding interference by the great vessels "g", limiting penetration of the anterior longitudinal ligament "l" and minimizing resection of the psoas muscle. The retractor 1000 may be inserted by impacting the proximal end of the retractor to drive the retractor into the intervertebral space.

FIG. 33 depicts retractor 1000 positioned within the intervertebral space "i" with the retractor arms 1200 arranged such that the first and second supporting surfaces 1200a, 1200b of each retractor arm 1200 respectively engage the opposed vertebral bodies "v<sub>1</sub>, v<sub>2</sub>". Upon insertion of retractor arms 1200, the vertebral bodies "v<sub>1</sub>, v<sub>2</sub>" are distracted whereby the retractor arms 1200 become firmly lodged within the intervertebral space "i". As noted above, upon insertion of the retractor arms 1200, the vertebrae "v<sub>1</sub>, v<sub>2</sub>" are distracted to a desired operative position. As depicted in FIG. 34, anchoring members 1100 are then advanced within their respective openings 1080 of rails 1060 and mounted within the vertebra "v<sub>1</sub>, v<sub>2</sub>" with the use of mounting tool 6000, e.g., an elongated driver

or the like, whereby the distal screw thread 1120 of each anchoring member engages the vertebral tissue. As a result, retractor 1000 is positively fixed to the vertebral column.

Referring now to FIG. 35, the drilling instrument 2000 is now utilized to prepare the disc space and vertebral end plates for insertion of the fusion implant. The cutting depth of drilling instrument 2000 is adjusted as desired (i.e., to correspond to the length of the fusion implant) by adjusting collars 2220, 2240 of the drilling instrument 2000. In particular, collar 2220 is moved to the desired position on threaded portion 2260 on the drill shaft 2020 and locking collar 2240 is moved adjacent the collar 2220 to lock the collar 2220 at the position. With the T-handle 5000 mounted to drilling instrument 2000, by corresponding reception of hex-head mounting structure 2300 within hex-head bore 5020 of handle 5000, the instrument is introduced into retractor sleeve 1020. Preferably, drill instrument 2000 is inserted within retractor sleeve 1020 whereby axial splines 2160 on the exterior surface of extension sleeve 2060 are received within internal recesses 1260 extending the length of the retractor sleeve 1020 and retractor arms 1200. T-shaped handle 5000 is thereafter rotated which causes drill shaft 2020 and drill bit 2040 to rotate. With reference to FIGS. 36 and 36A, as drill shaft 2020 rotates, it also advances within retractor sleeve 1020 due to the threaded engagement of threaded portion 2280 on the drill shaft 2020 with internal threaded portion 1240 of retractor sleeve 1020 thereby advancing the drill bit 2040 into the adjacent vertebrae "v<sub>1</sub>, v<sub>2</sub>" to form a circular bore in the end plates of the adjacent vertebrae. In addition, as drill shaft 2020 advances it also drives extension sleeve 2060 distally within the adjacent vertebrae. Due to the interengagement of axial splines 2160 and longitudinal recesses 1260, extension sleeve 2060 advances without rotating whereby cutting surfaces 2180a at the distal end of extension sleeve 2060 cuts through a shearing action into the adjacent

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vertebrae "v<sub>1</sub>, v<sub>2</sub>". Thus, the cutting surfaces 2180a of the cutting arms 2180 are retained at the desired angular orientation adjacent retractor arms 1200. The arcuate orientation of the cutting surfaces 2180a of extension sleeve 2060 in combination with drill bit 2040 form a general elliptical opening in the adjacent vertebrae "v<sub>1</sub>, v<sub>2</sub>". It is to be noted that drilling instrument is advanced within retractor sleeve 1020 until positioning collar 2220 engages the proximal end of the retractor sleeve as shown in FIG. 36 - the length of travel of drilling instrument being predetermined by adjusting collars 2220, 2240 as discussed above.

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Subsequent to the drilling process, fusion implant 100 is packed with bone growth inducing substances as is conventional in the art and end cap 104 is threaded into a threaded recess of implant body 102. The fusion implant 100 is then mounted on insertion instrument 4000 by cooperative engagement of the engaging structure 4020 of the insertion instrument with the implant 100 as discussed above.

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Referring now to FIG. 37, insertion instrument 4000 and mounted implant 100 is introduced within retractor 1000 and advanced to a position adjacent the vertebral bodies "v<sub>1</sub>, v<sub>2</sub>". Thereafter, insertion instrument 4000 is rotated via T-shaped handle 5000 which is mounted to the instrument 4000 to thereby cause corresponding rotation of fusion implant 3000. As fusion implant 3000 rotates, the thread 3080 of the implant body 3020 bites into the vertebral bodes "v<sub>1</sub>, v<sub>2</sub>". Continued rotation of insertion tool 4000 causes implant 3000 to be self-tapped within the preformed bore. Implant 3000 is released from its mounting to insertion tool 4000 and the instrument 4000 and retractor 1000 are removed from the disc area.

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FIGS. 38-39 depict fusion implant 100 inserted within the intervertebral space "i". As shown, fusion implant 100 forms a strut across the intervertebral space "i" to maintain the adjacent vertebrae "v<sub>1</sub>, v<sub>2</sub>" in appropriate

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spaced relation during the fusion process. The implant is thus preferably inserted at an angle of between about 15 degrees and about 45 degrees, and more preferably at about 30 degrees to the longitudinal axis of the spine and to the right of the great vessels as view anteriorly. As also shown, in the inserted position of implant 100, the major axis "a" is in general parallel relation to the vertebral end plates thus presenting the great arc or surface area of implant body 102 to contact and support the adjacent vertebrae. Over a period of time, the adjacent vertebral tissue communicates through apertures 112 with the bone growth inducing substances within the interior cavity of implant 100 to form a solid fusion. Thus only one implant is required.

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While the above description contains many specifics, these specifics should not be construed as limitations on the scope of the disclosure, but merely as exemplifications of preferred embodiments thereof. For example, the fusion implant 100, 100' could also be used for thoracic and cervical vertebrae. Those skilled in the art will envision many other possible variations that are within the scope and spirit of the disclosure as defined by the claims appended hereto.

**WHAT IS CLAIMED IS:**

5           1. An apparatus for facilitating the fusion of adjacent bone structures comprising an implant member configured for insertion within a space defined between adjacent bone structures, the implant member including an entry end portion and a trailing end portion and defining a longitudinal axis, the implant member including at least a longitudinal portion having a generally elliptical cross-sectional dimension transverse to the longitudinal axis.

10           2. The apparatus according to claim 1 wherein the external surface portion includes a threaded portion to facilitate insertion within the space defined between adjacent bone structures.

3. The apparatus according to claim 2 wherein the implant member includes a hollow interior cavity dimensioned to accommodate bone growth inducing substances.

15           4. The apparatus according to claim 3 wherein the implant member includes a plurality of apertures extending through an external surface portion in communication with the interior cavity, to thereby permit bone ingrowth to facilitate fusion of the adjacent bone structure.

20           5. The apparatus according to claim 2 wherein the entry end portion of the implant member defines a generally circular cross-sectional dimension transverse to the longitudinal axis to facilitate positioning between the adjacent bone structures.

6. The apparatus according to claim 5 wherein the entry end portion includes a closed entry end surface.

7. The apparatus according to claim 3 wherein the implant member includes an exterior surface portion having at least one flute formed therein.

5 8. The apparatus according to claim 7 wherein the one flute is disposed adjacent the entry end portion and is formed in the threaded portion.

9. The apparatus according to claim 8 wherein the entry end portion includes a closed entry end surface.

10 10. The apparatus according to claim 9 wherein the one flute extends to the closed entry end surface.

11. The apparatus according to claim 1 further including an end cap mountable to the trailing end portion of the implant member to enclose the interior cavity.

15 12. The apparatus according to claim 1 wherein the implant member is configured for insertion within the intervertebral space defined between adjacent vertebrae.

13. An apparatus for facilitating fusion of adjacent vertebrae comprising an elongated implant member configured and dimensioned for insertion within an intervertebral space defined between adjacent vertebrae, the implant member including at least a longitudinal section having a transverse cross-sectional dimension defining a generally elliptical configuration, the implant member including an internal cavity for accommodating bone growth inducing substances and having a plurality of apertures extending through an external wall portion thereof in communication with the internal cavity.

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14. The apparatus according to claim 13 wherein the implant member includes an external threaded portion for facilitating insertion within the intervertebral space.

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15. The apparatus according to claim 14 wherein the implant member includes at least one flute, the one flute being formed in the threaded portion.

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16. The apparatus according to claim 14 wherein the implant member includes an entry section having a closed entry end surface.

17. The apparatus according to claim 16 including at least one flute formed in the entry end surface.

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18. The apparatus according to claim 14 wherein the implant member includes an entry end section, the entry end section having a transverse cross-sectional dimension defining a generally circular configuration.

19. The apparatus according to claim 14 further including an end cap mountable to the implant member to enclose the internal bore.

20. The apparatus according to claim 18, wherein the implant includes a trailing end portion and an intermediate portion between the trailing end portion and the entry end portion, the entire intermediate portion and [trailing end portion] having a transverse cross-sectional dimension defining a generally elliptical configuration.

21. A method for fusion of adjacent vertebrae, comprising the steps of:

10 accessing the intervertebral space defined between adjacent vertebrae;

15 positioning a fusion apparatus into the intervertebral space, the fusion apparatus including an implant body having at least a longitudinal section defining a general elliptical transverse cross-section with a major axis greater than a minor axis; and

permitting bone ingrowth into contacting surfaces of the implant body to facilitate fusion of the adjacent vertebrae.

22. The method according to claim 21 wherein the step of positioning includes arranging the implant member within the intervertebral space whereby the major axis of the implant member is in general parallel relation with the vertebral end faces to the adjacent vertebrae.

23. The method according to claim 22 including the step of introducing bone growth inducing substances within an internal cavity defined within the implant body whereby the adjacent vertebrae communicates with the bone growth inducing substances to form a solid fusion.

5 24. The method according to claim 23 wherein the implant body includes an exterior wall portion having apertures extending therethrough wherein the step of permitting bone ingrowth includes permitting bony tissue of the adjacent vertebrae to grow through the apertures to communicate with the bone growth inducing substances.

10 25. The method according to claim 24 wherein the implant body includes an external threaded portion, wherein the step of positioning includes screwing the implant body into a preformed receiving bore formed into the adjacent vertebrae.

15 26. The method according to claim 25 wherein the external threaded portion of the implant body includes a cutting thread wherein the step of screwing the implant body includes advancing the implant body within the preformed receiving bore whereby the cutting thread deburrs bone tissue to self-tap the implant body within the preformed receiving bore.

20 27. The method according to claim 21, wherein the implant is inserted laterally with respect to the longitudinal axis of the spine.

28. A method for fusion of adjacent vertebrae comprising the steps of:

accessing the intervertebral space of the lumbar spine defined between adjacent vertebrae;

5 positioning a fusion apparatus into the intervertebral space of the lumbar spine and at an angle of between about 15° and about 45° with respect to the longitudinal axis of the spine and to the right of the great vessels when viewed anteriorly.

29. A system for drilling a bore in adjacent vertebrae to facilitate the insertion of a fusion implant, which comprises:

10 a surgical retractor including a sleeve member having proximal and distal end portions and defining a longitudinal opening, the distal end portion configured for insertion at least partially into an intervertebral space between adjacent opposed vertebrae to distract the adjacent vertebrae; and

15 a drill instrument positionable within the longitudinal opening of the surgical retractor, the drill instrument including:

20 an elongate member defining at least one distal cutting surface; and

a drill member disposed within the elongate member and having a distal cutting head, the drill member being rotatably movable within the elongate member and being longitudinally fixed to the elongate member such that advancement of the drill member within the adjacent vertebrae causes corresponding advancement of the elongate member such that the distal cutting surface and the distal cutting head cooperate to cut a bore in the adjacent vertebrae.

30. The system according to claim 29 wherein the distal end portion of the sleeve member of the surgical retractor includes two spaced apart retractor arms having first and second supporting surfaces.

5 31. The system according to claim 30 wherein the elongate member of the drill instrument includes first and second diametrically opposed distal cutting surfaces.

10 32. The system according to claim 29 including alignment means for aligning and maintaining the elongate member of the drill instrument at a predetermined angular orientation within the sleeve member of the surgical

33. The system according to claim 32 wherein the alignment means includes at least one groove defined in the sleeve member of the surgical retractor, the at least one groove dimensioned to accommodate a corresponding spline of the elongate member.

15 34. The system according to claim 29 wherein the sleeve member of the surgical retractor includes an internal threaded portion, the internal threaded portion threadably engageable with an external threaded portion of the drill instrument whereby rotation of the drill instrument causes distal translation of the drill instrument relative to the surgical retractor.

20 35. The system according to claim 29 including at least one anchoring member associated with the elongate member and moveable relative to the elongated member to facilitate mounting to vertebrae.

36. A system for drilling a bore in adjacent vertebrae to facilitate the insertion of a fusion implant, which comprises:

a surgical retractor including a sleeve member having proximal and distal end portions and defining a longitudinal opening, the distal end portion configured for insertion at least partially into an intervertebral space between adjacent opposed vertebrae to distract the adjacent vertebrae, the sleeve member including an internal threaded portion;

10 a drill instrument positionable within the longitudinal opening of the surgical retractor, the drill instrument including a drill member having a distal cutting head and an external threaded portion engageable with the internal threaded portion of the retractor whereby rotation of the drill instrument causes distal translation of the drill instrument relative to the surgical retractor.

15 37. The system according to claim 36 wherein the distal end portion of the sleeve member of the surgical retractor includes two spaced apart retractors arms having first and second supporting surfaces.

38. A method for performing a surgical procedure, comprising the steps of:

20 providing a surgical retractor including an elongate member having proximal and distal end portions and defining a longitudinal opening, the distal end portion including two spaced apart retractor arms having first and second supporting surfaces;

inserting the retractor arms within the intervertebral space whereby the first and second supporting surfaces of each retractor arm respectively engage and distract the adjacent opposed vertebrae;

mounting the surgical retractor to the adjacent vertebrae by securing anchor members associated with the surgical retractor to the adjacent vertebrae; and

5 performing the surgical procedure adjacent the distracted vertebrae.

39. The method according to claim 38 wherein the step of performing includes introducing surgical instrumentation within the opening of the surgical retractor to perform the surgical procedure.

40. A method for fusing adjacent vertebral bodies, comprising the steps of:

10 a) accessing the intervertebral disc space;  
b) providing a retractor including a retractor sleeve having proximal and distal end portions, the distal end portion having opposed retractor arms extending in a general longitudinal direction;

15 c) positioning the retractor arms within the intervertebral disc space whereby first and second supporting surfaces of each arm contact opposed vertebra bodies;

20 d) introducing a drill instrument into the retractor sleeve and advancing the drill instrument within the sleeve to the disc space, the drill instrument including an elongate member defining at least one distal cutting surface and a drill member rotatably mounted within the elongate member and having a distal cutting head;

e) actuating the drill instrument such that the distal cutting head of the drill member and the distal cutting surface of the elongate member are advanced into the adjacent vertebrae to cooperate and cut a bore in the vertebra bodies;

- 5 f) removing the drill instrument from the sleeve; and  
g) introducing a fusion implant into the bore.

10 41. The method according to claim 40 wherein the bore formed in the vertebral bodies defines a general elliptical cross-sectional dimension and wherein the step of introducing includes inserting a fusion implant having a general elliptical cross-sectional dimension into the bore.

42. The method according to claim 41 wherein in a final inserted position of the fusion implant, a major axis of the implant is in the transverse direction generally parallel to the vertebral end plates.

15 43. A surgical retractor instrument comprising an elongated member having proximal and distal end portions and defining a longitudinal passage for reception of a surgical instrument, the distal end portion having first and second retractor arms extending in a general longitudinal direction, each retractor arm having first and second supporting surfaces for engaging opposed tissue portions, each retractor arm defining a dimension between the first and second supporting surfaces sufficient to distract the opposed tissue portions upon insertion thereof, and at least one anchoring member associated with the elongated member and moveable relative to the elongated member to facilitate mounting to the tissue portion.

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44. The surgical retractor according to claim 43 wherein the at least one anchoring member includes a distal screw thread wherein rotation of the one anchoring member advances the screw thread into the tissue portion.

5 45. The surgical retractor according to claim 43 including an outer rail extending longitudinally along an outer surface of the elongated member, the rail defining a longitudinal opening for at least partial reception of the at least one anchoring member.

10 46. The surgical retractor according to claim 43 including first and second anchoring members associated with the elongated member.

15 47. The surgical retractor according to claim 46 including first and second diametrically opposed outer rails extending longitudinally along an outer surface of the elongated member, the first and second rails each defining a longitudinal opening for reception of respective first and second anchoring members.

20 48. The surgical retractor according to claim 43 wherein the first and second supporting surfaces of each retractor arm are in general parallel relation.

49. The surgical retractor according to claim 48 wherein each retractor arm has a tapered end portion for facilitating insertion within an intervertebral space.

50. The surgical retractor according to claim 48 wherein the first and second supporting surfaces of each retractor arm are in general parallel relation to a longitudinal axis of the elongated body.

5 51. A surgical drill instrument for drilling a bore in bony tissue comprising an elongate member defining a longitudinal axis and having a longitudinal passageway and a drill member positioned within the longitudinal passageway of the elongate member and mounted for rotational movement therein, the elongate member defining at least one distal cutting surface dimensioned to cut bony tissue, the drill member including a distal cutting head, the drill member operatively connected to the elongate member such that rotation and advancement of the drill member causes corresponding advancement of the elongate member such that the one distal cutting head surface of the elongate member and the distal cutting head of the drill head cooperate to form a substantially elliptical bore in the bony tissue upon advancement therein.

10 15 52. The surgical retractor according to claim 51 wherein the elongate member includes first and second diametrically opposed distal cutting surfaces.

53. The surgical retractor according to claim 52 wherein the distal cutting surfaces are arcuately shaped.

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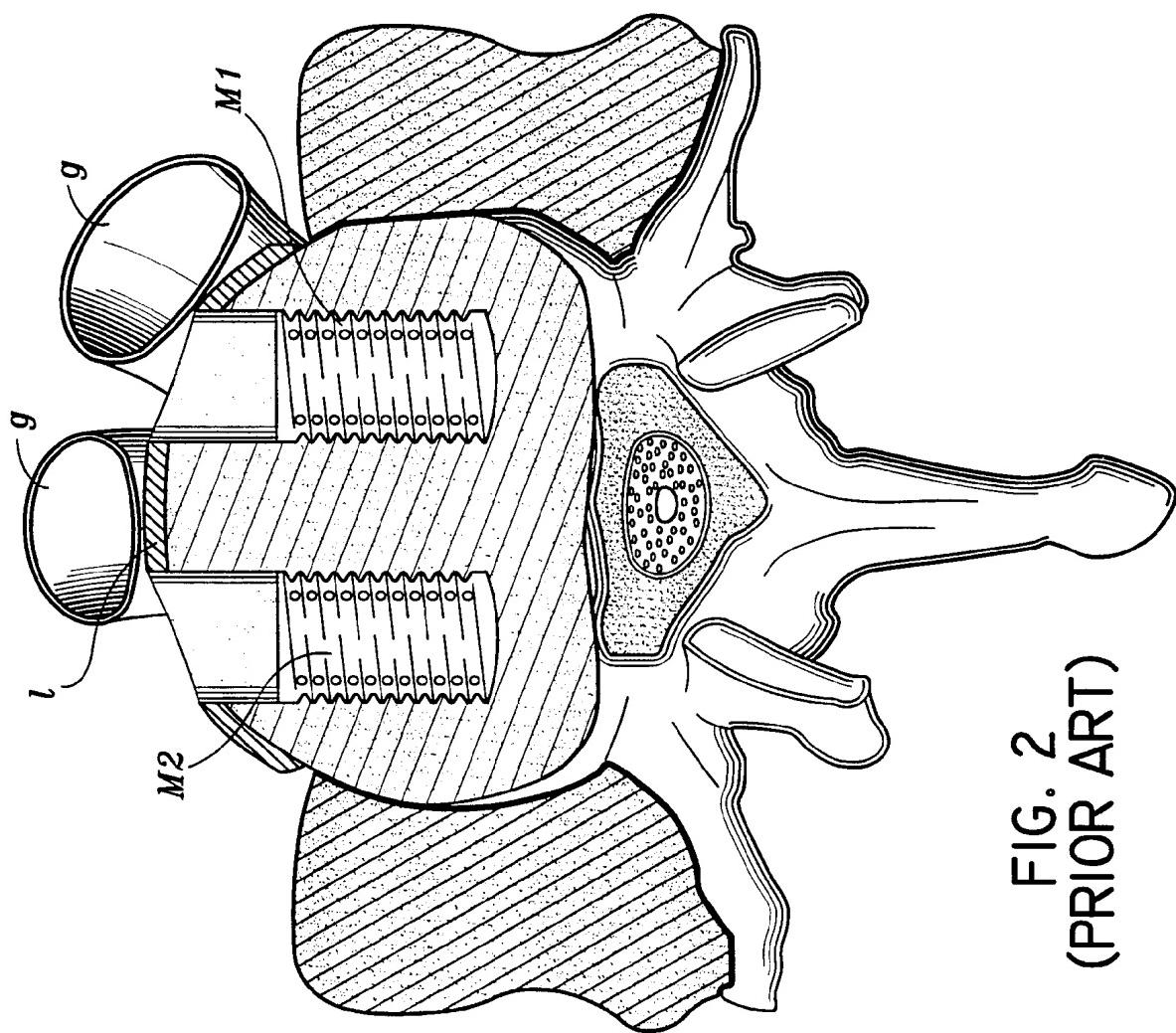


FIG. 2  
(PRIOR ART)

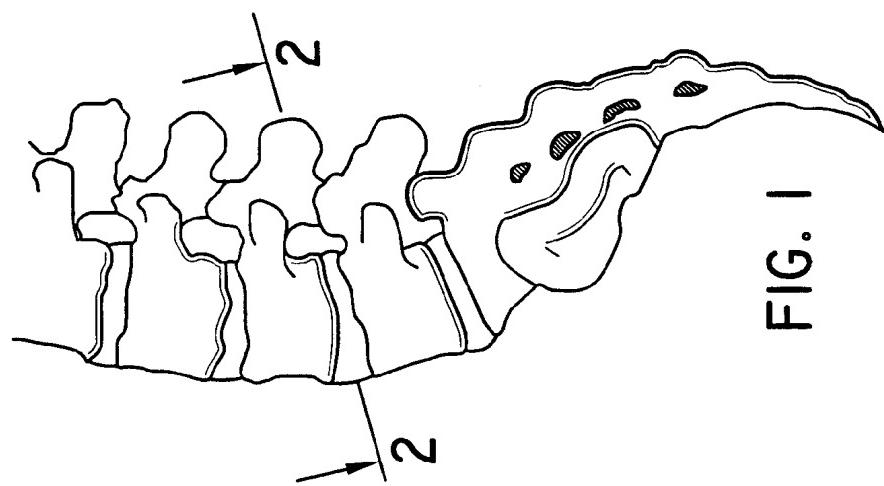


FIG. 1

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FIG. 3

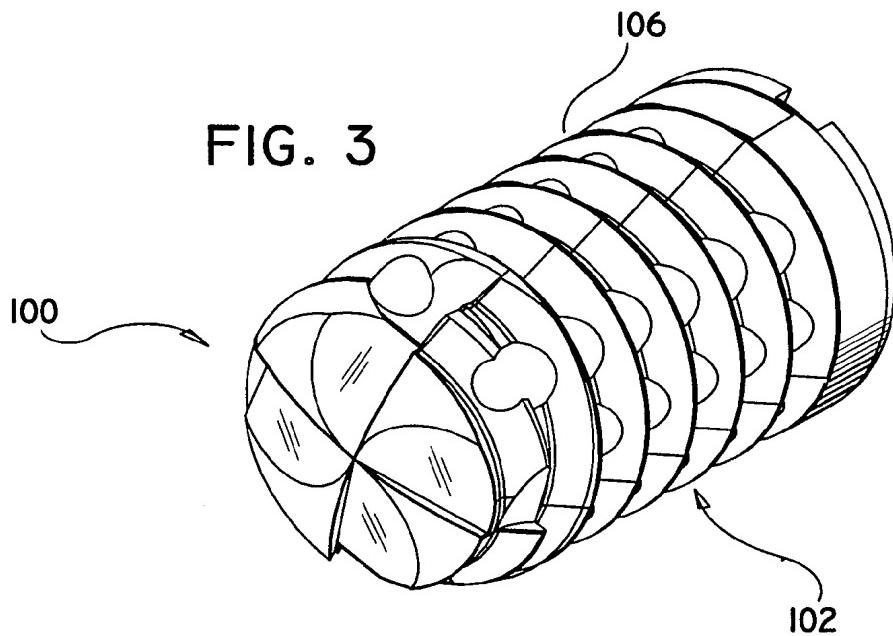
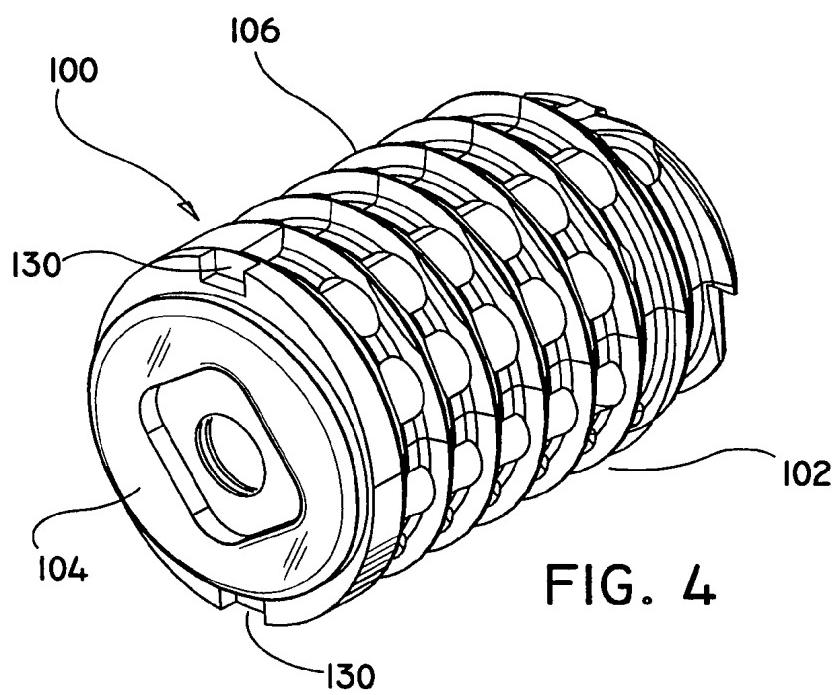
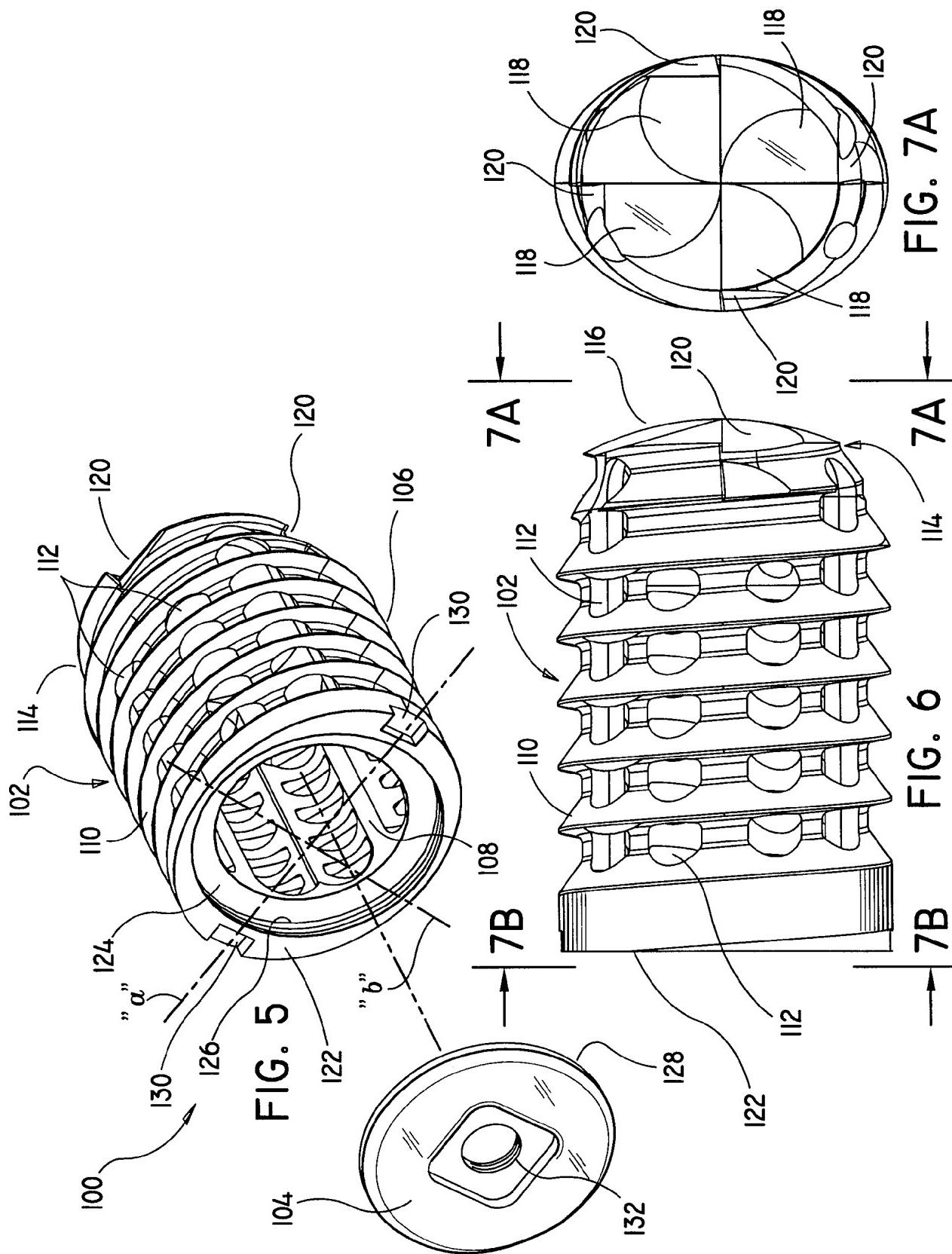


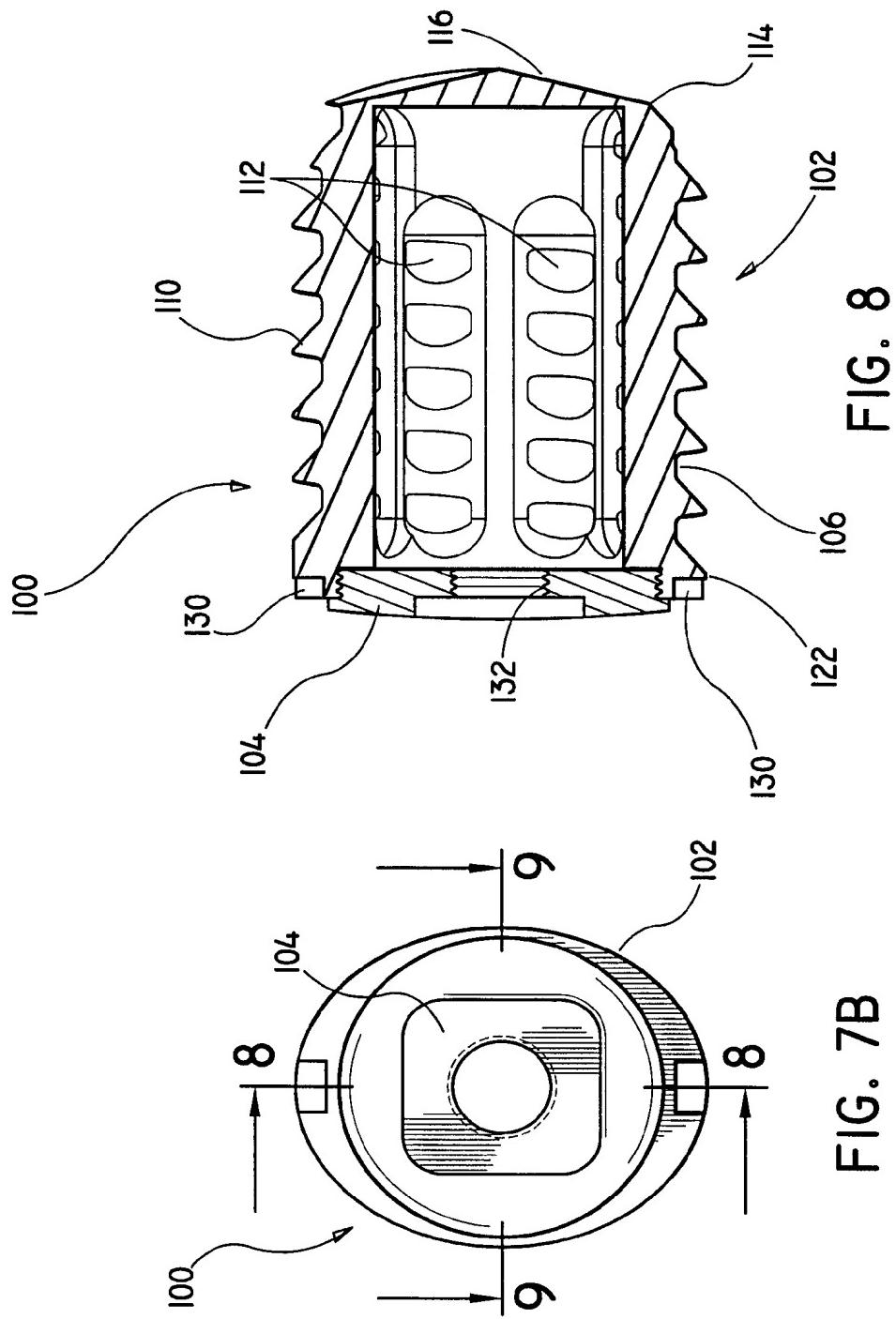
FIG. 4

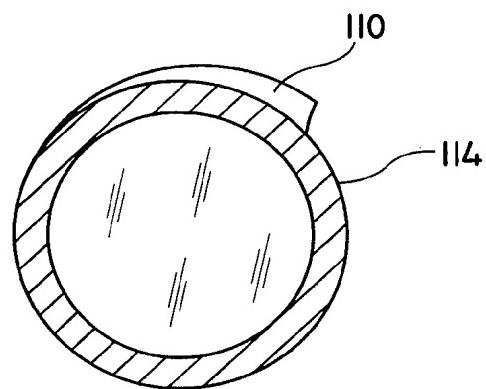
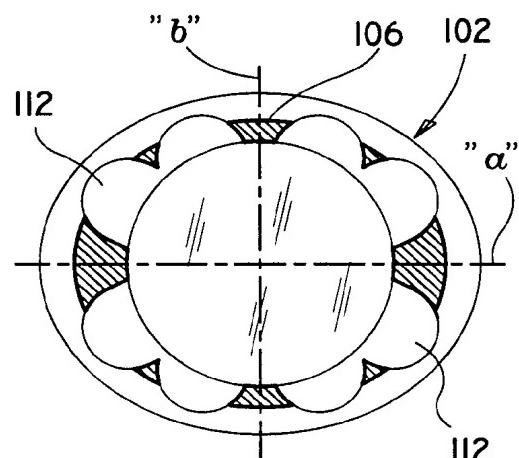
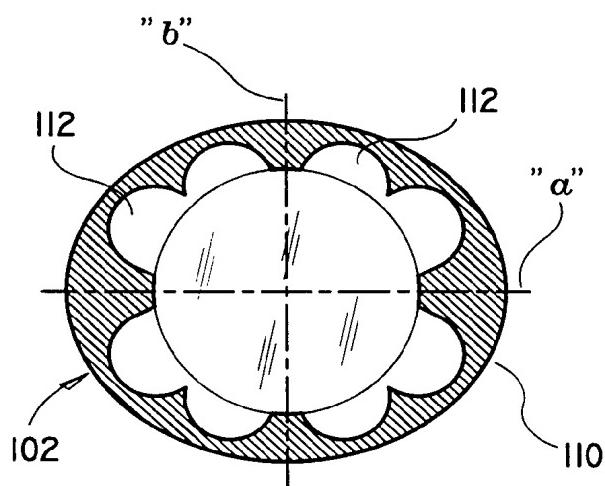
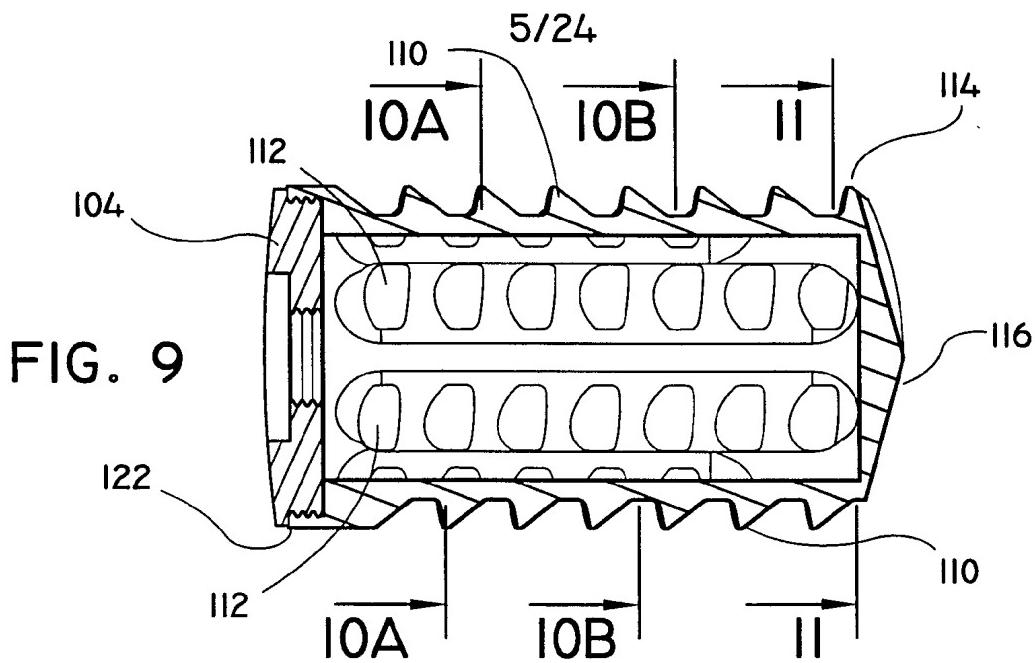


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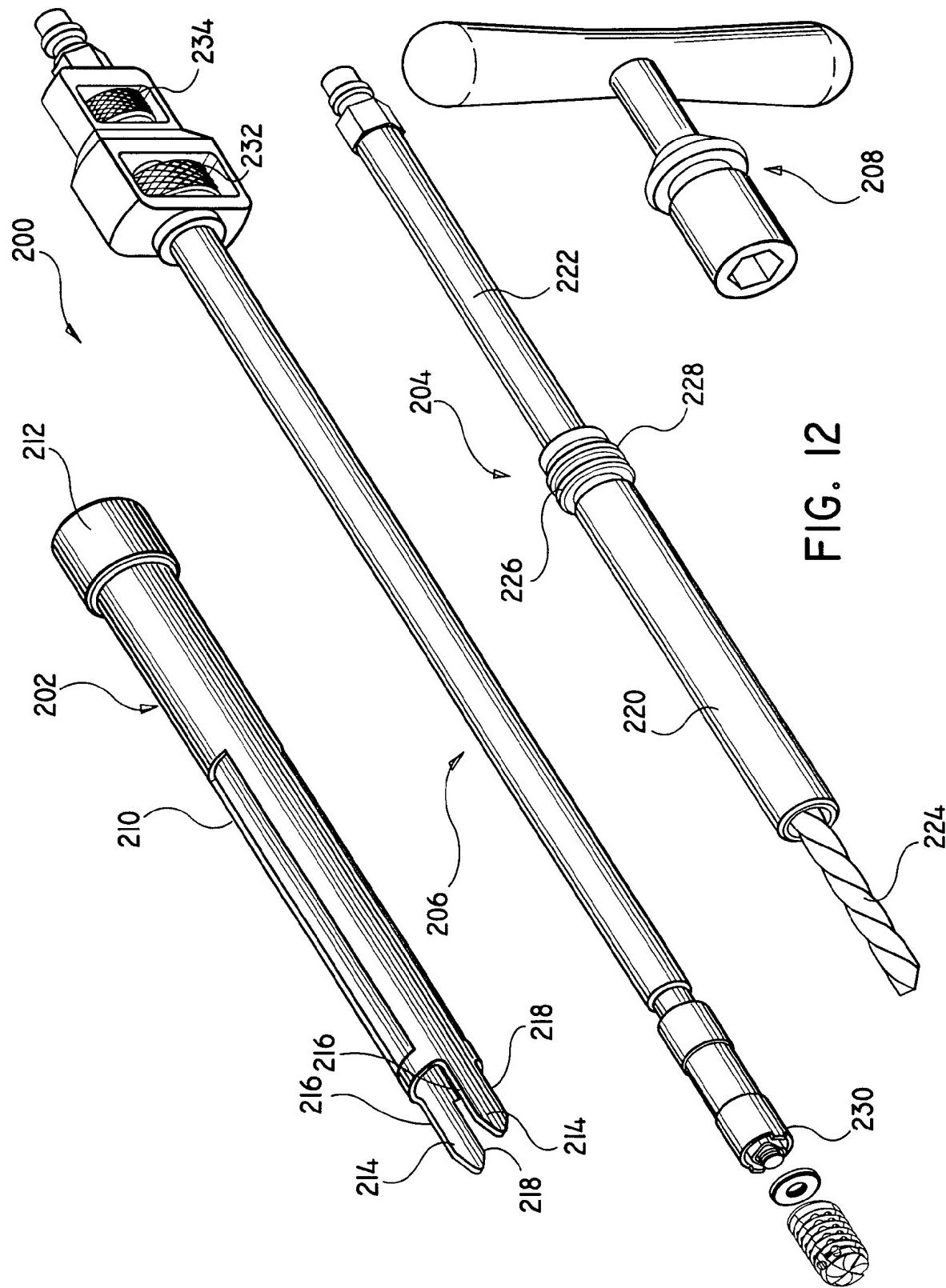


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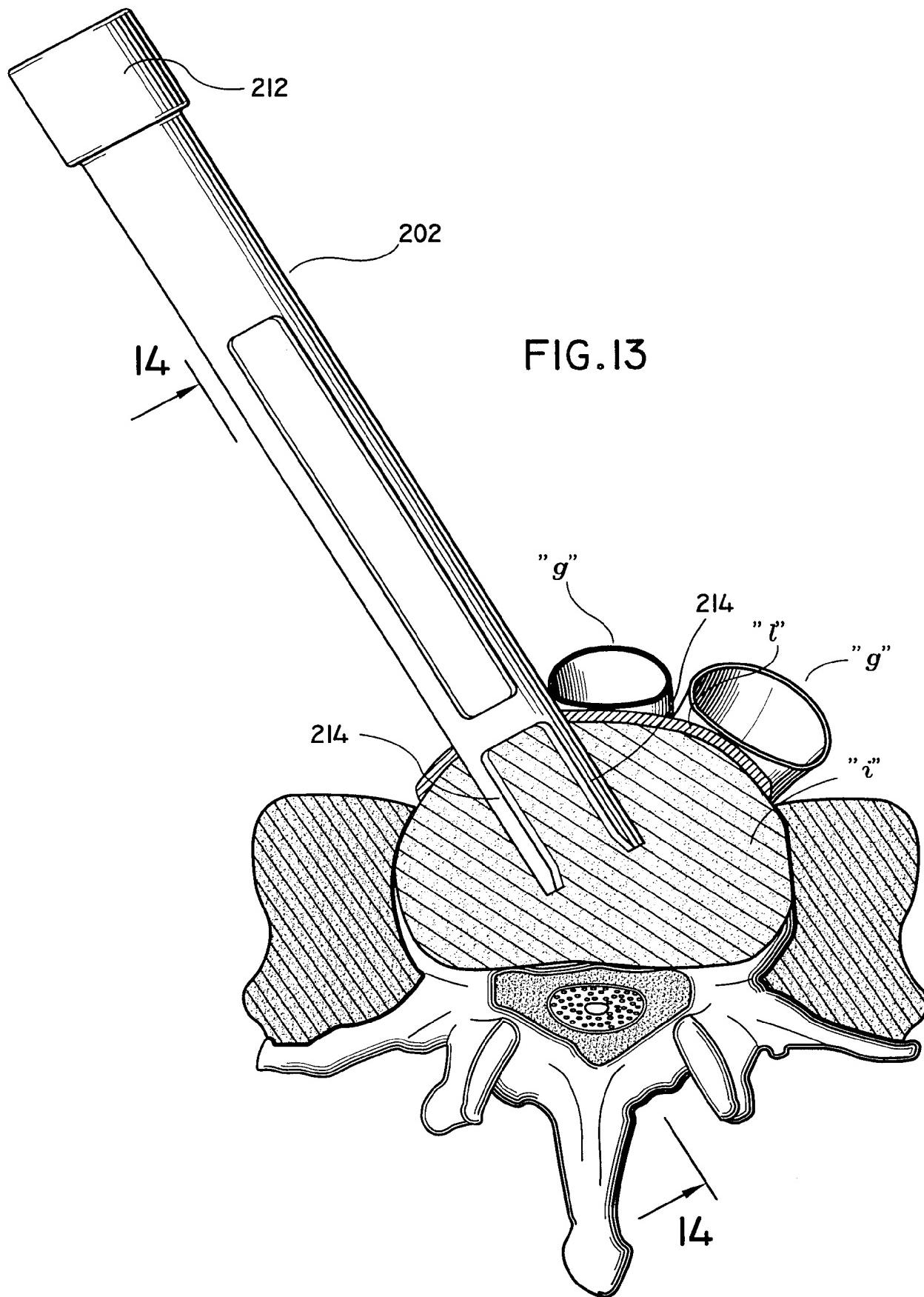




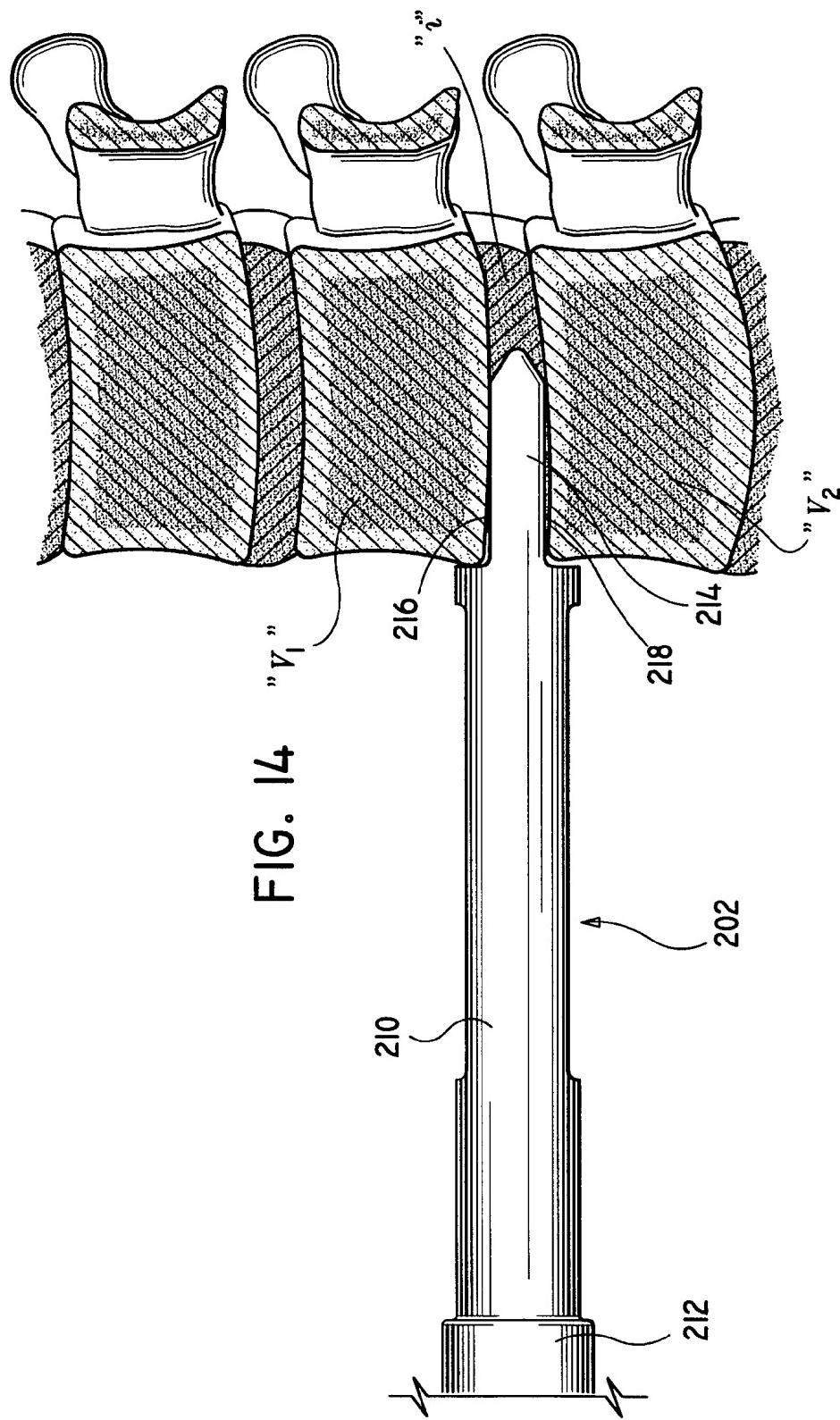
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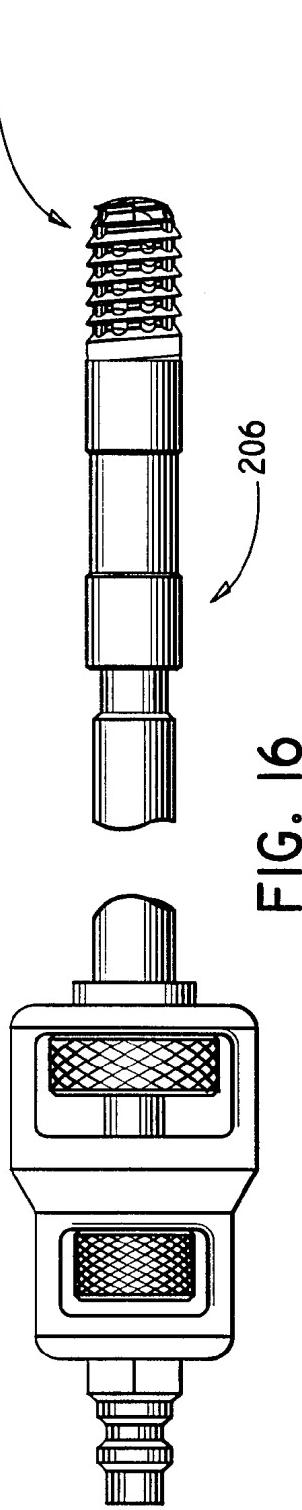
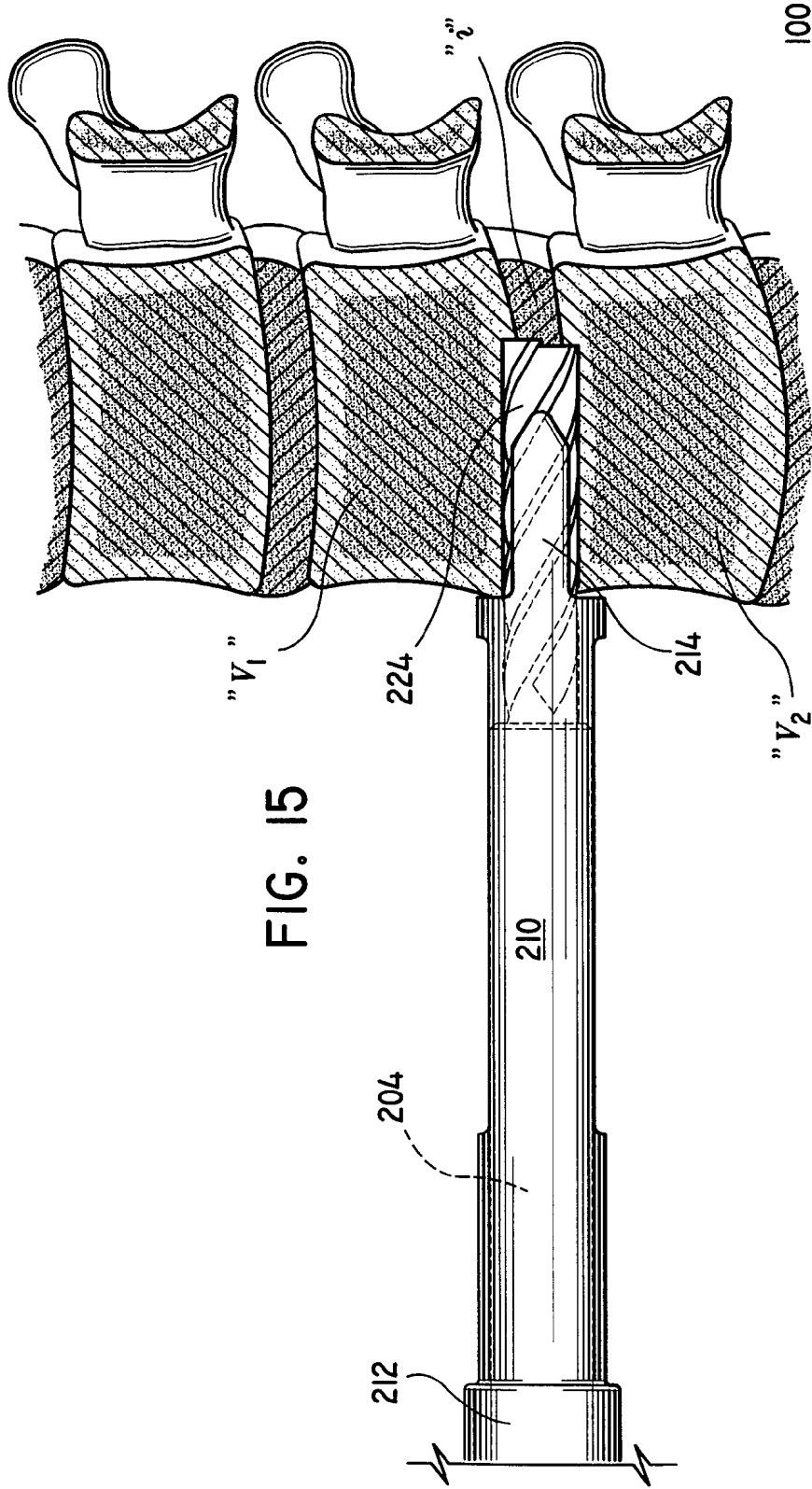
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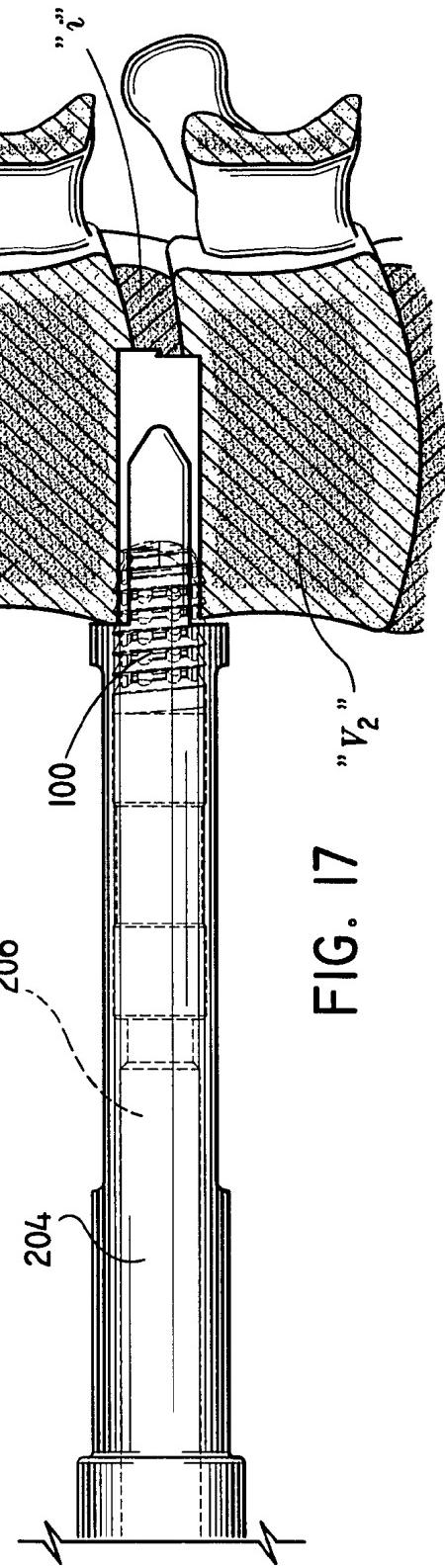
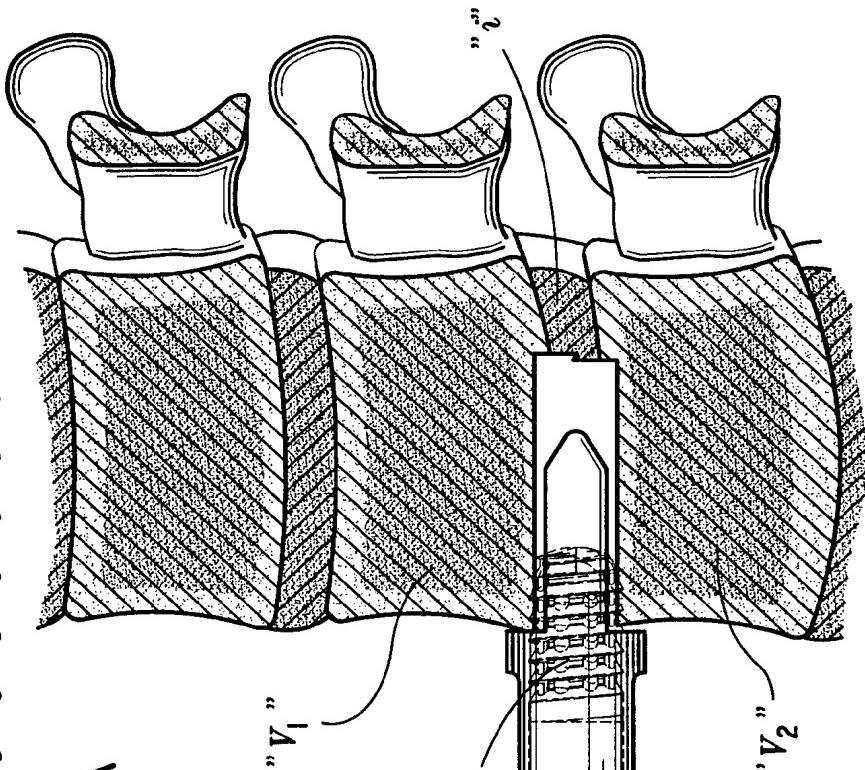
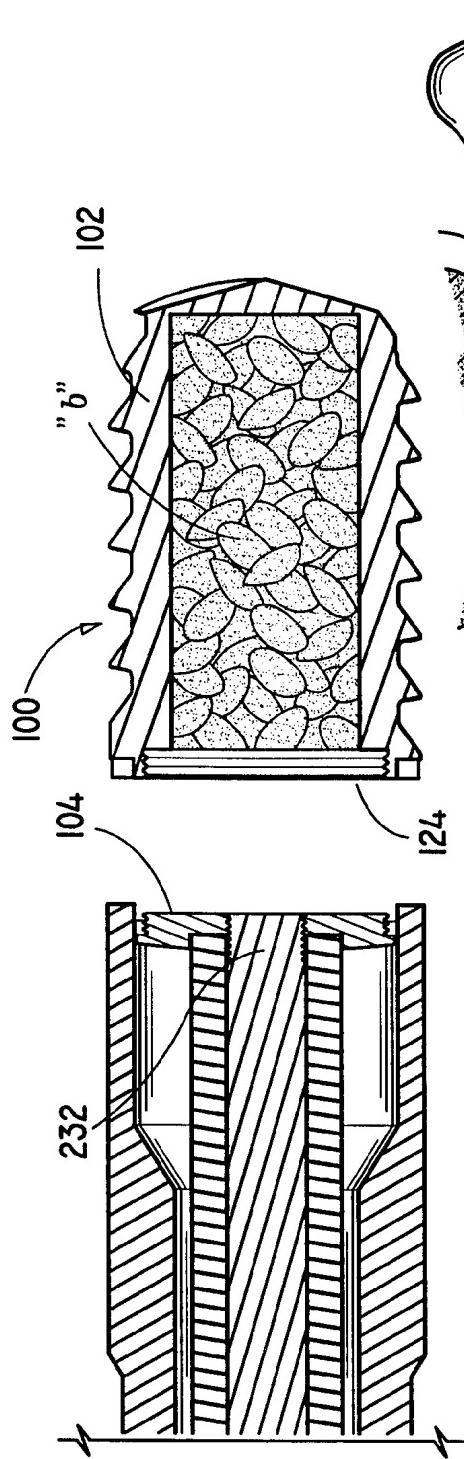
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FIG. 18

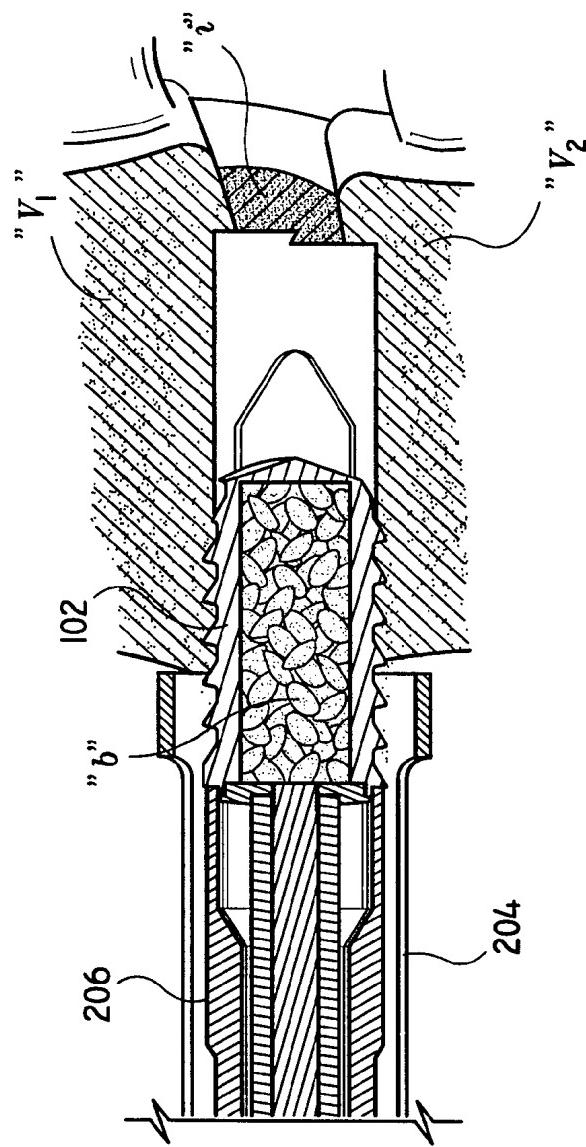
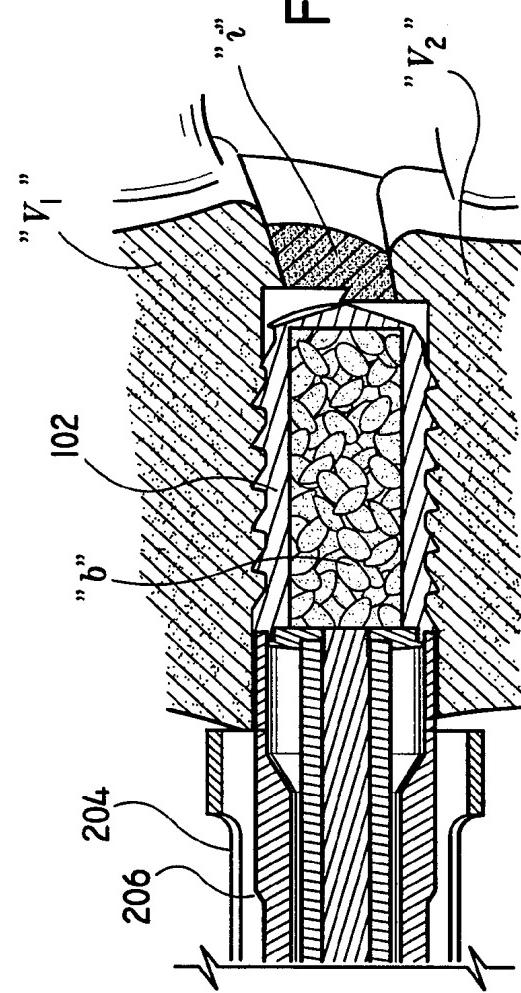


FIG. 19



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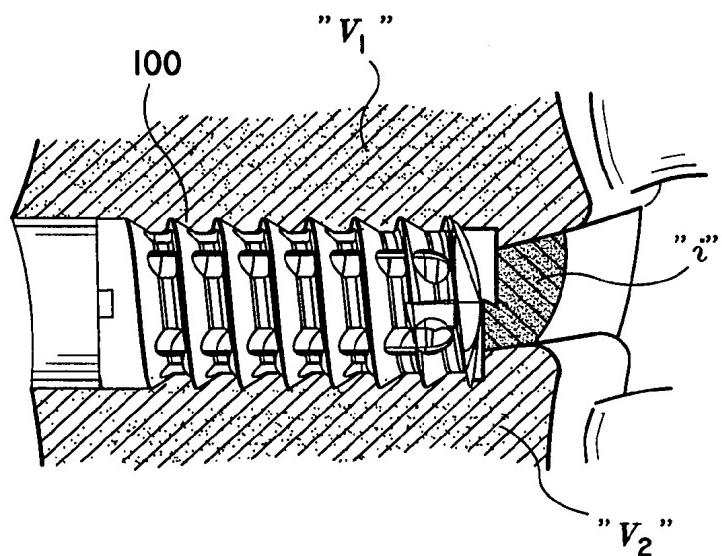


FIG. 20

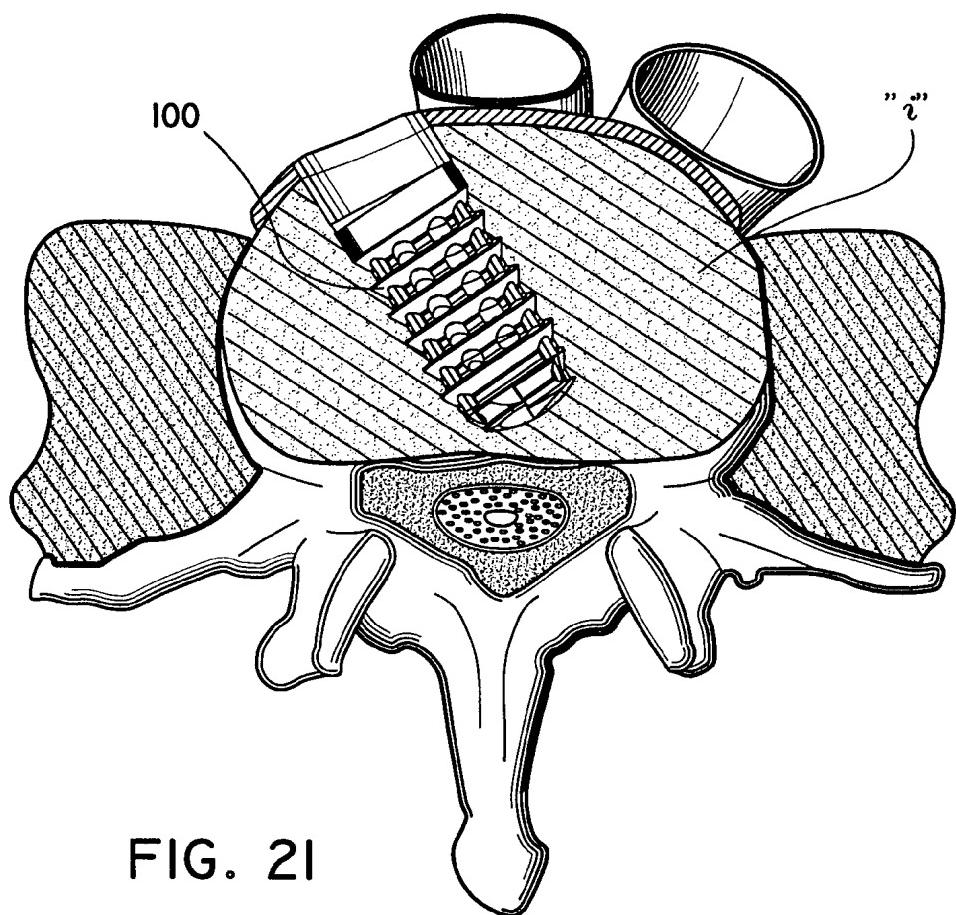
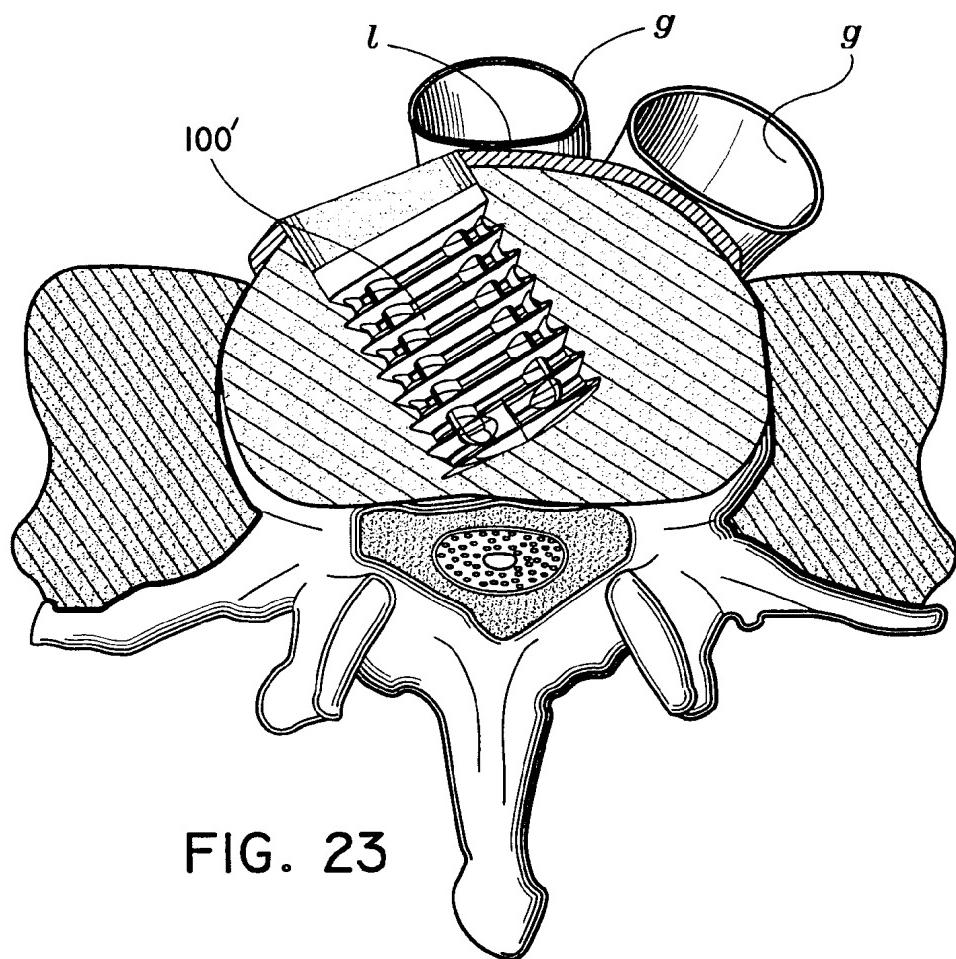
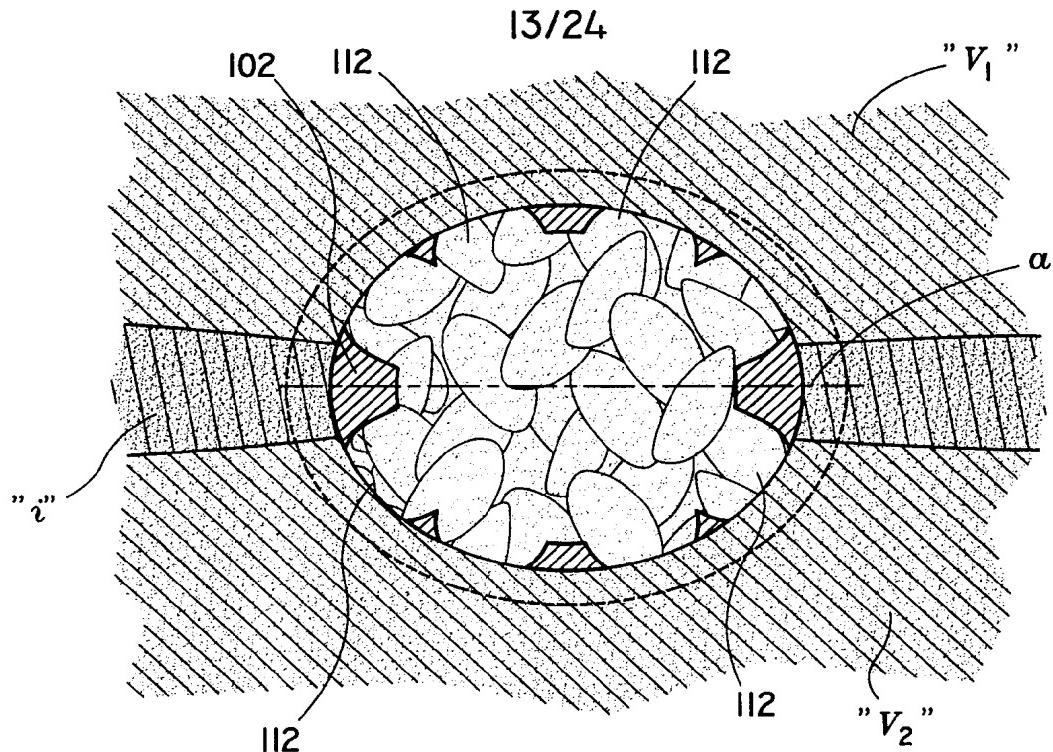
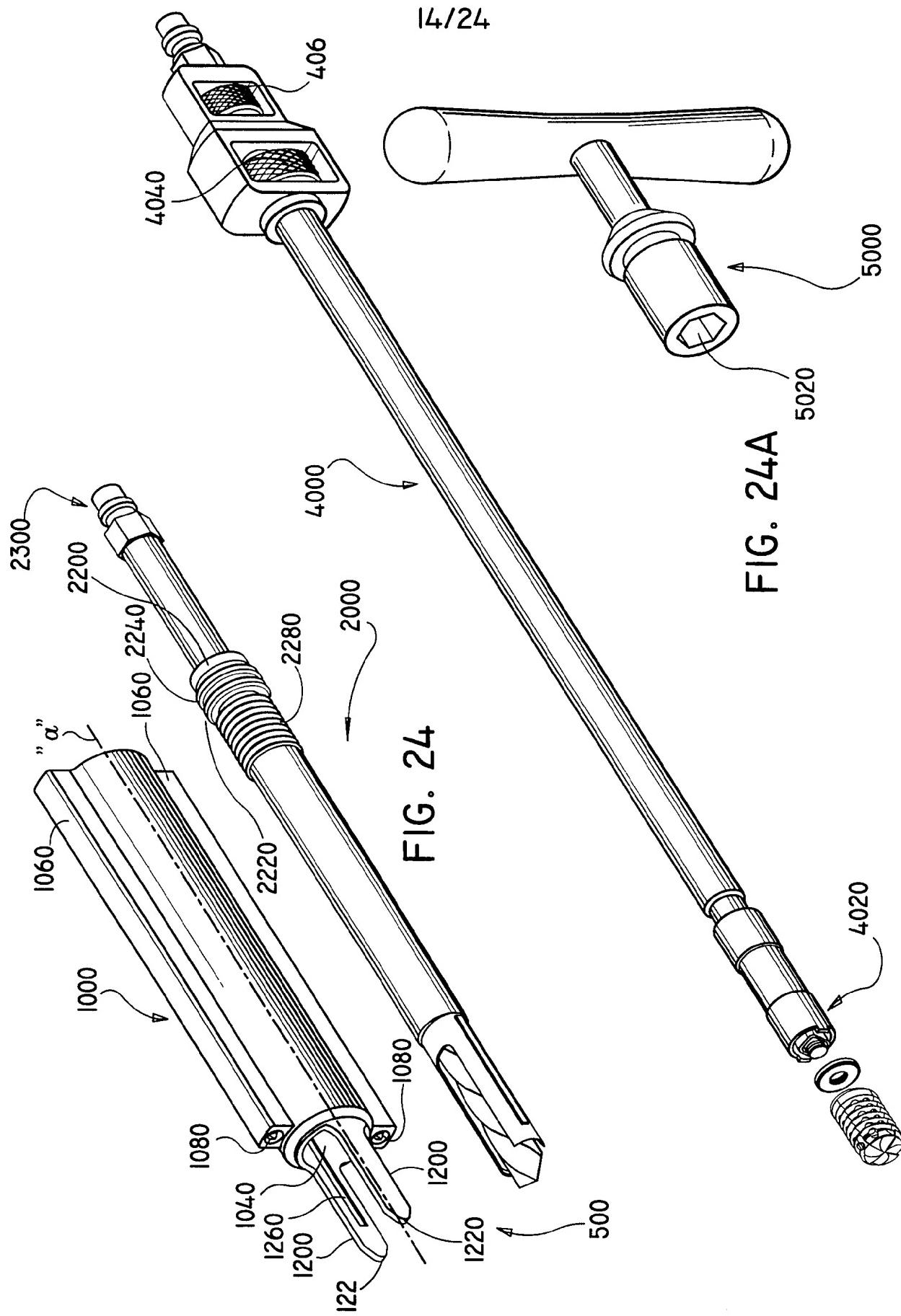
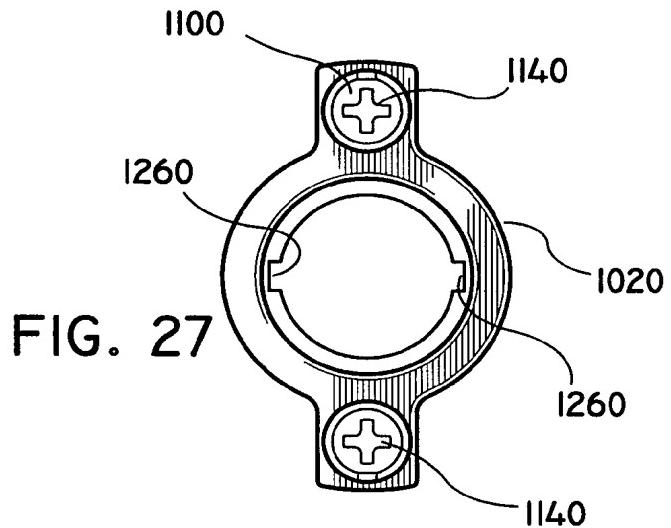
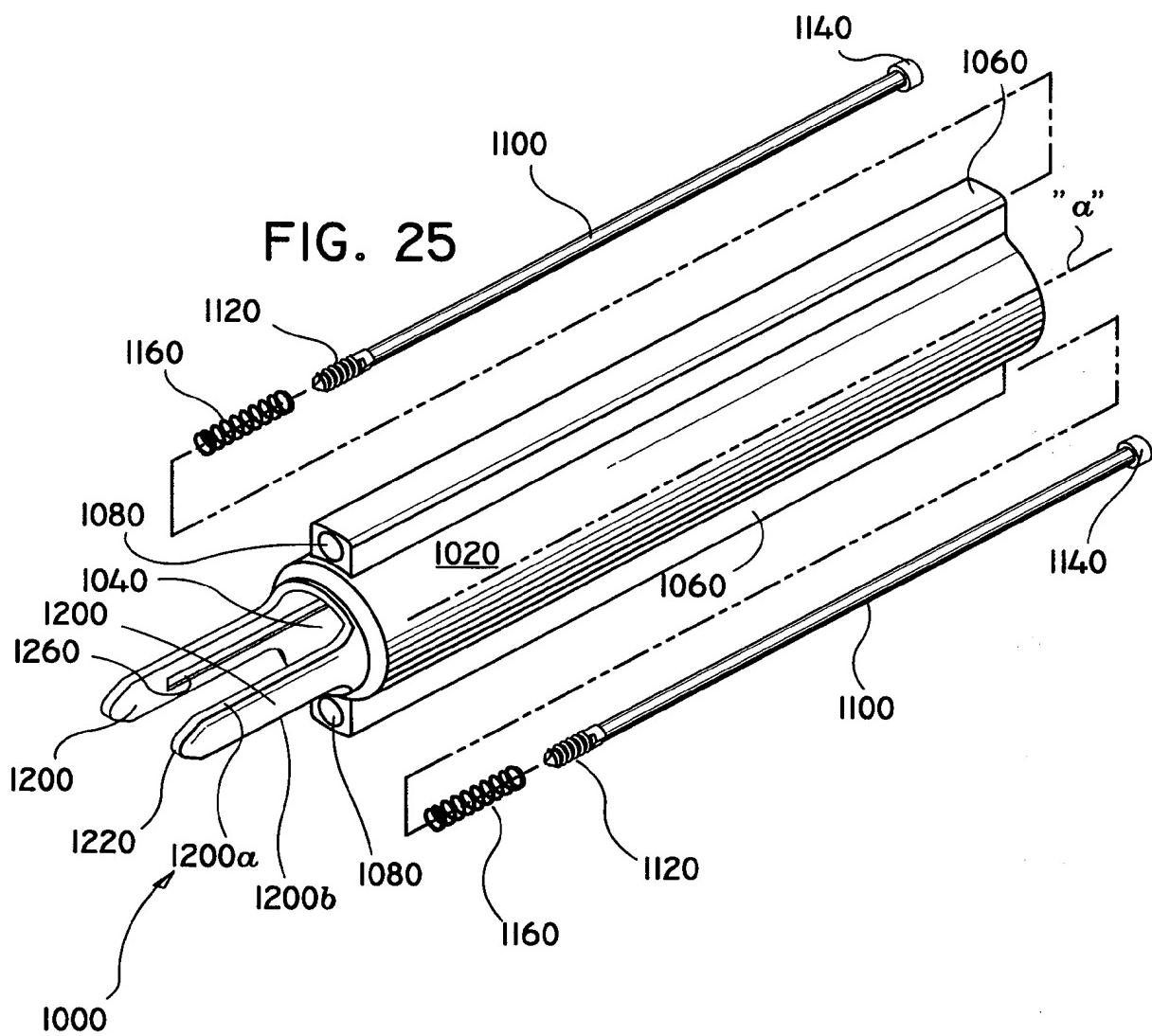


FIG. 21

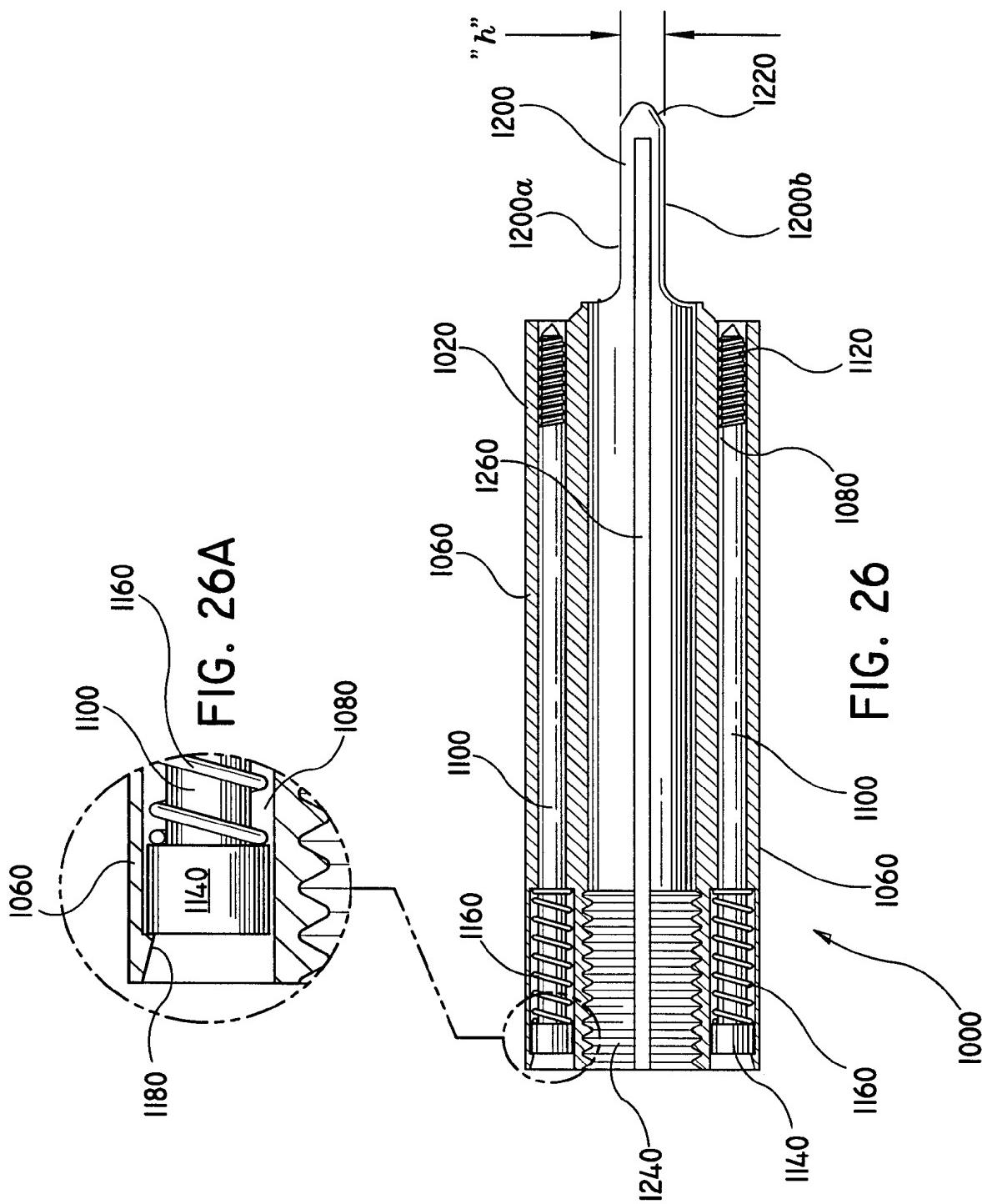


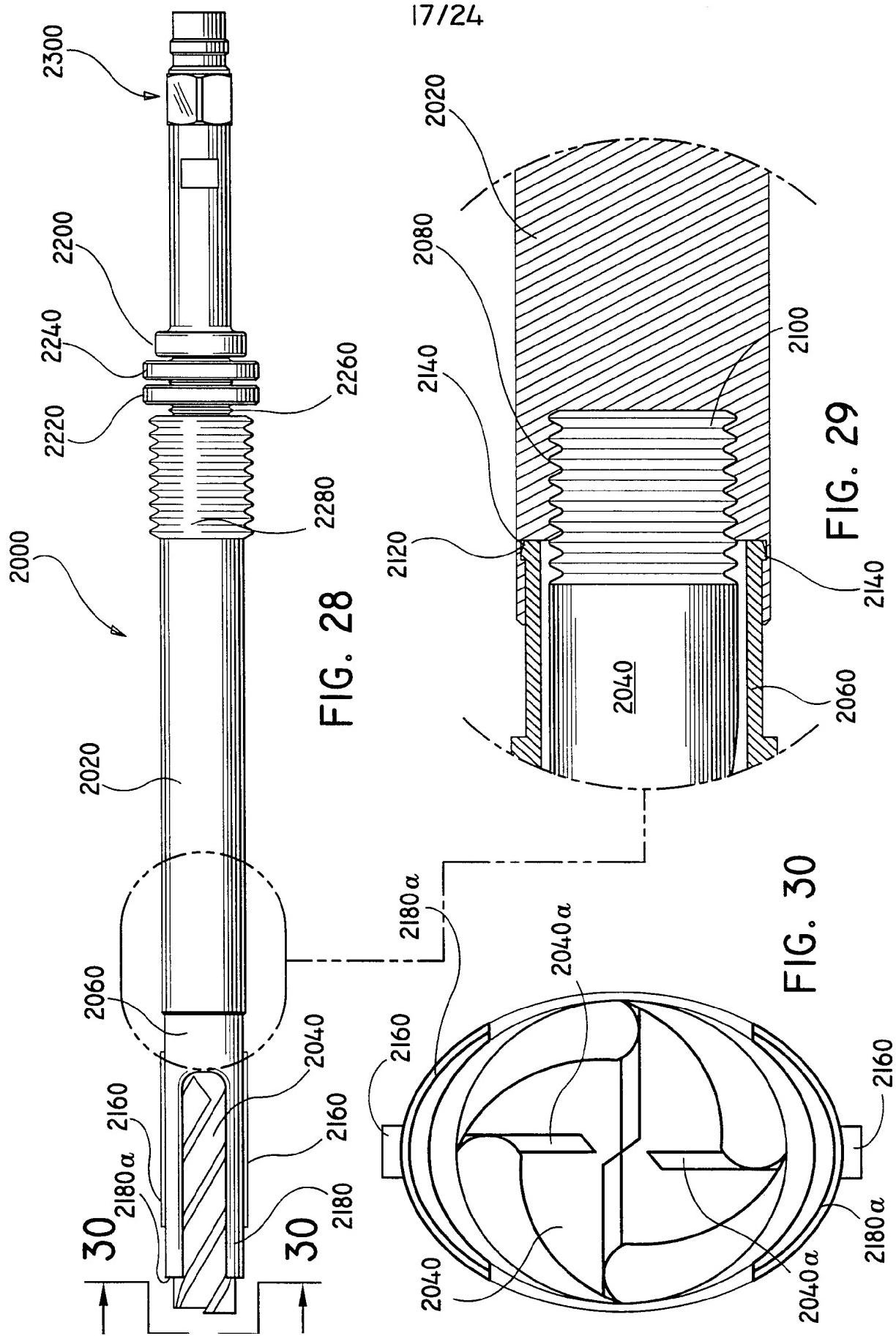


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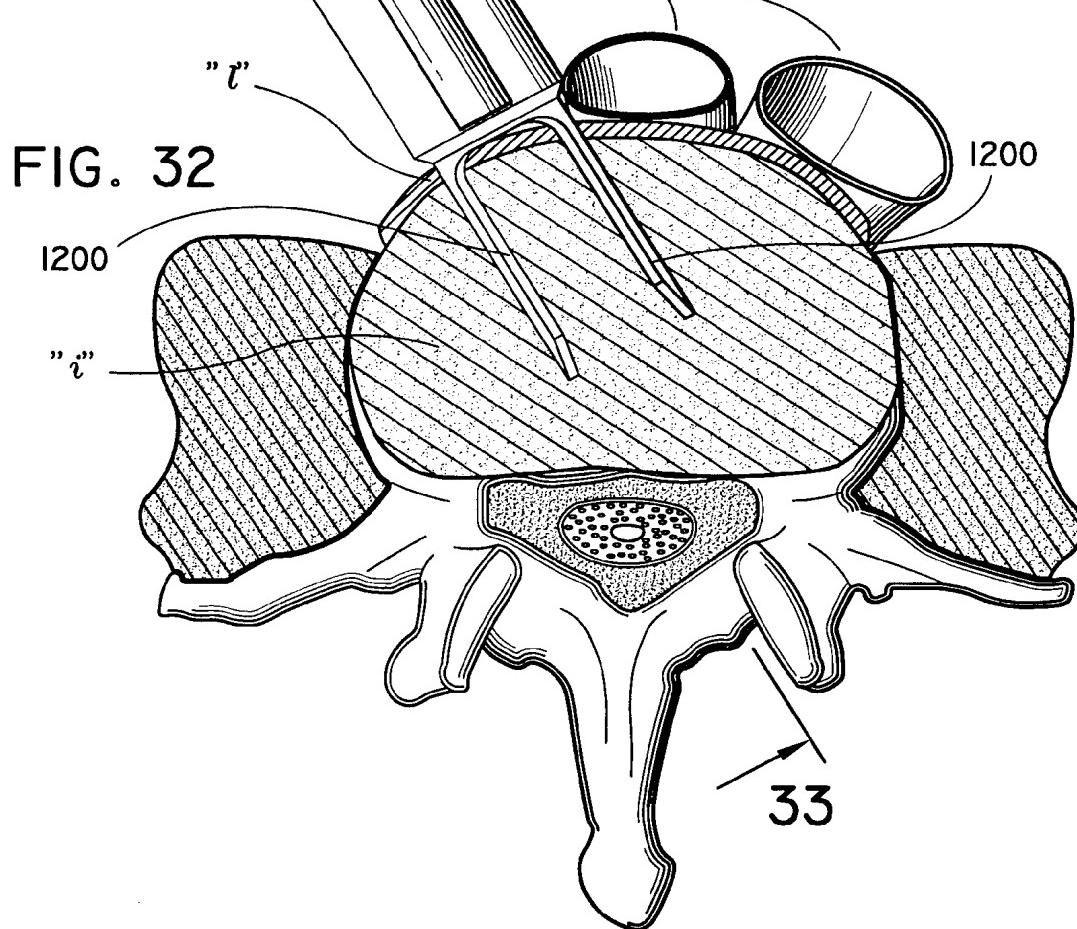
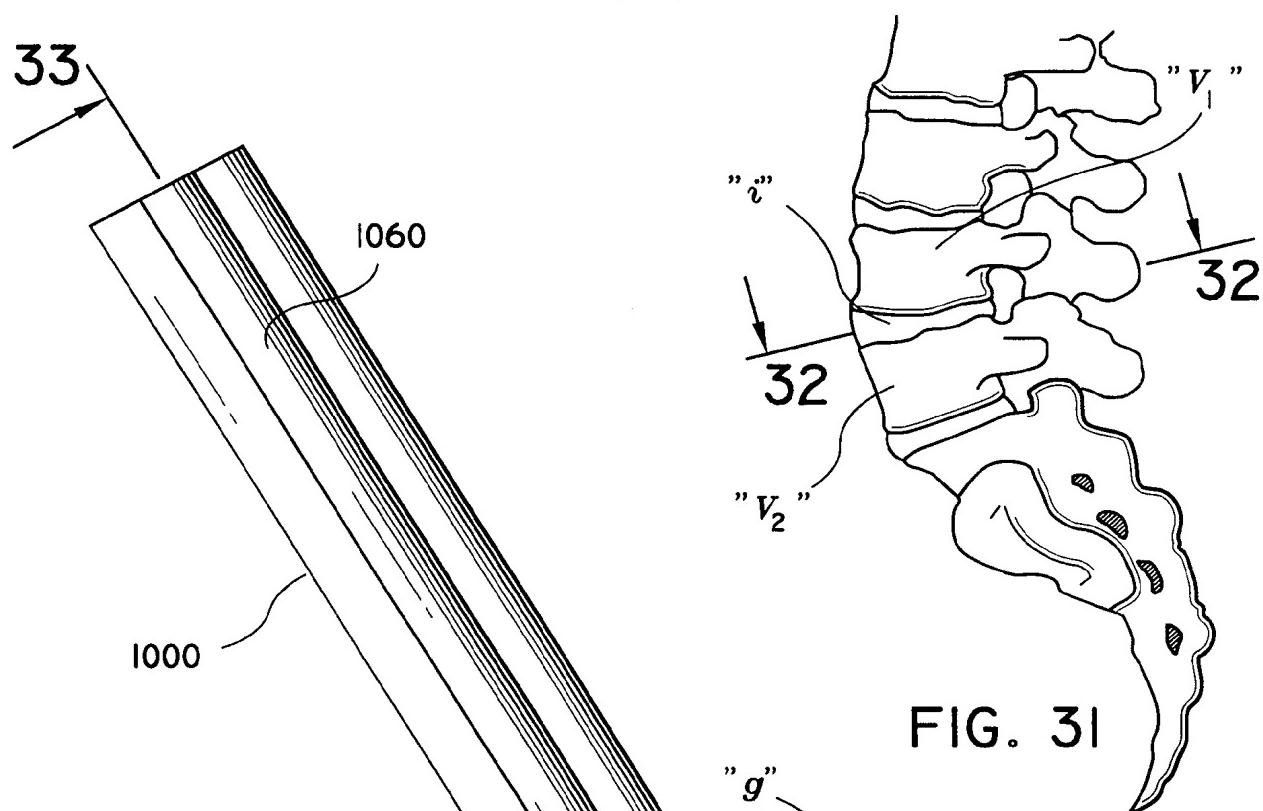


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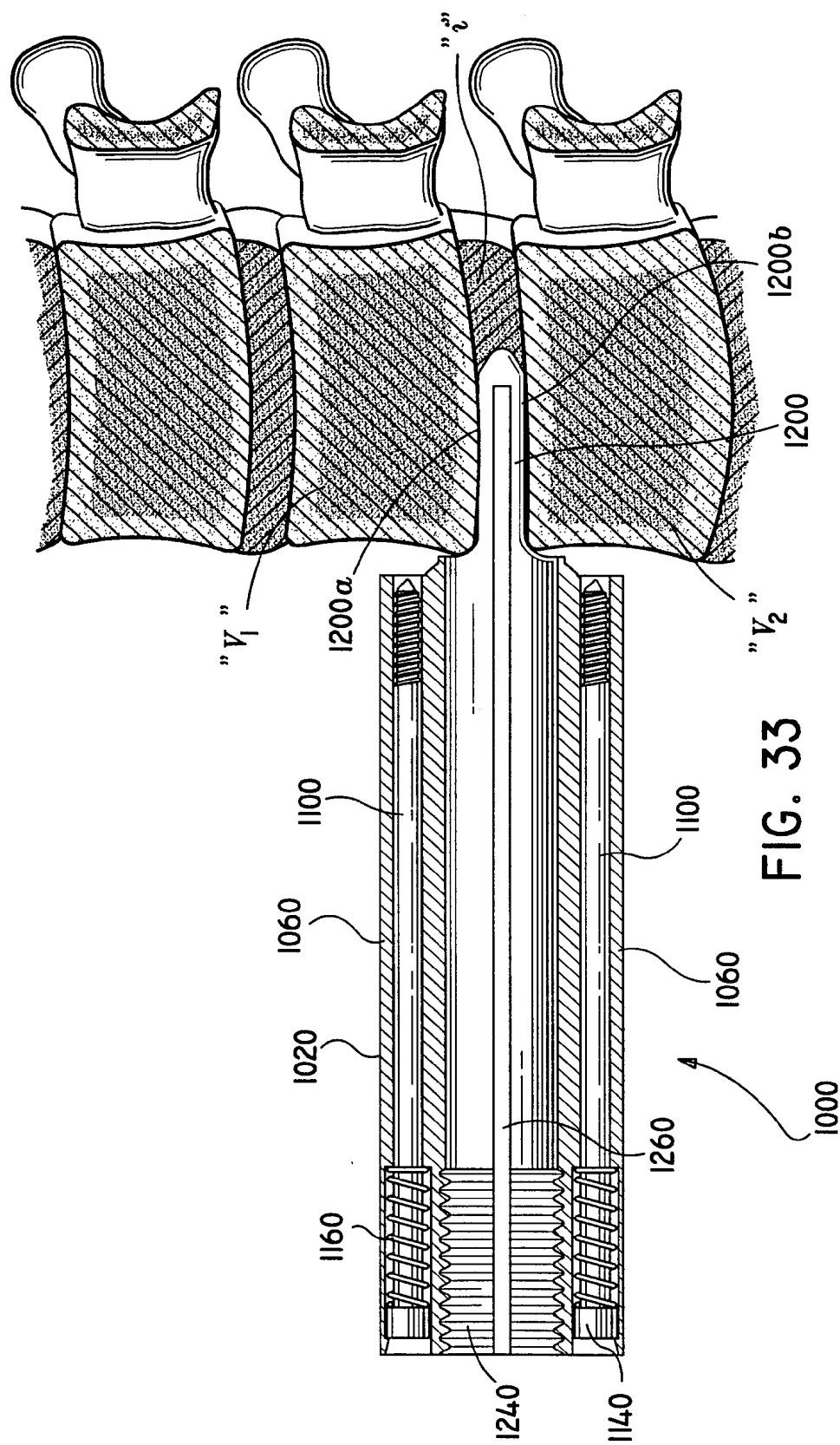


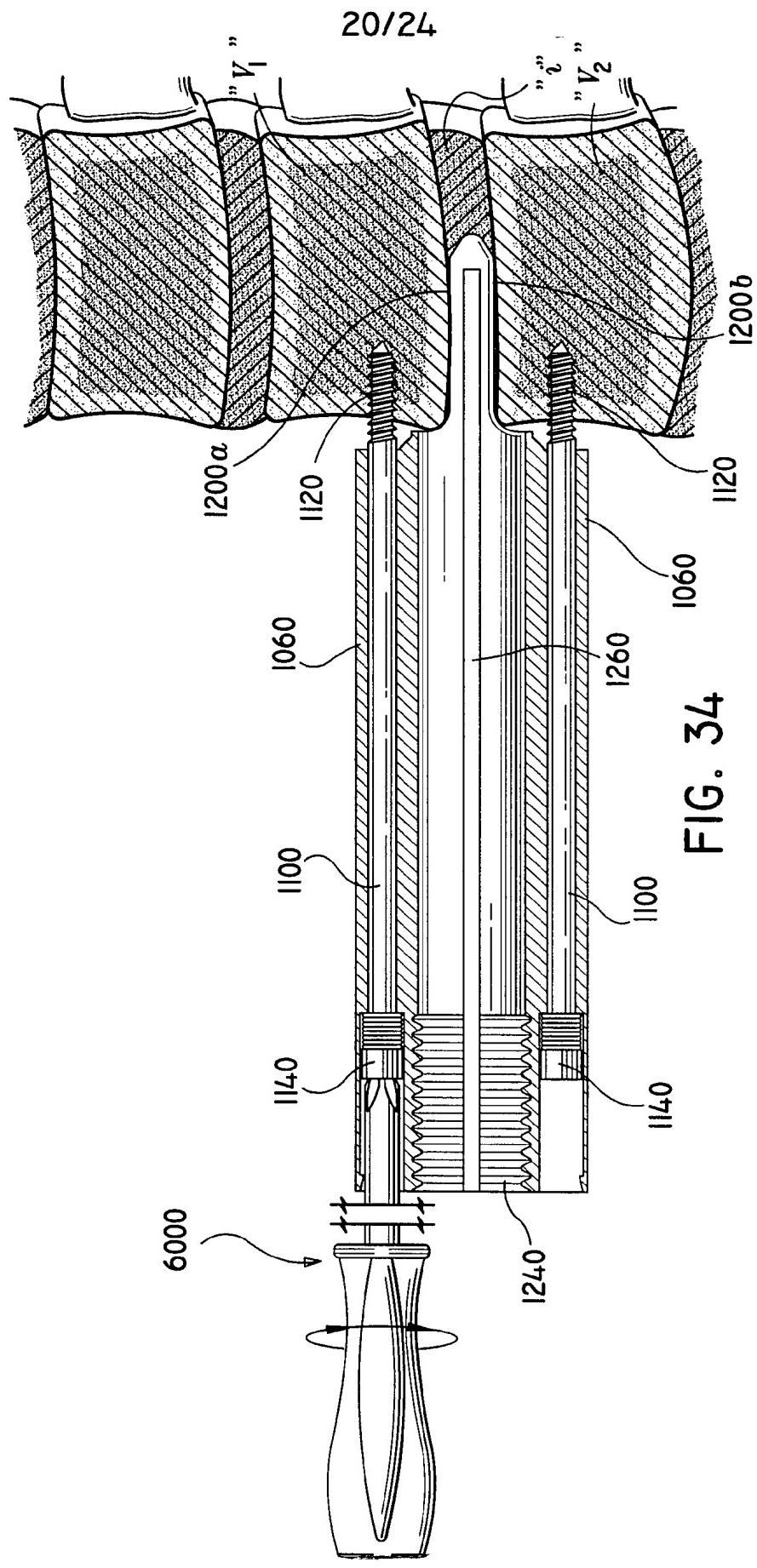


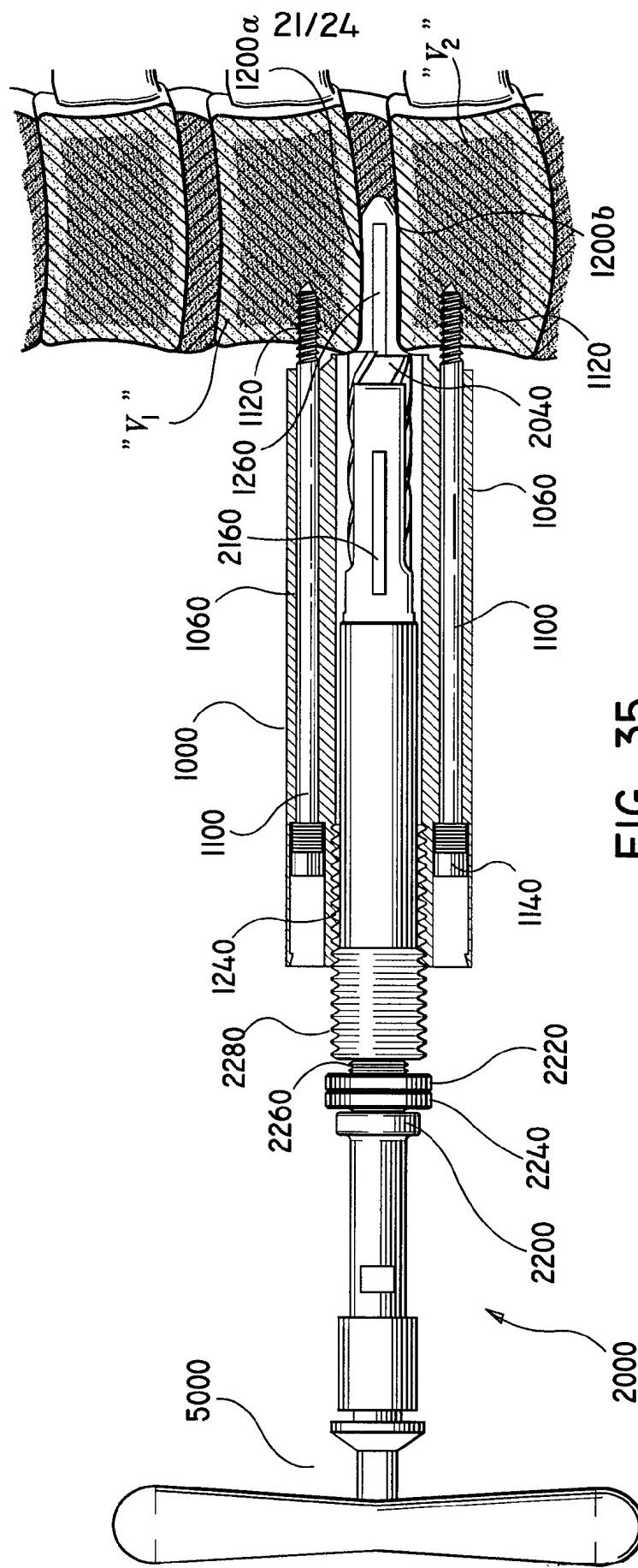
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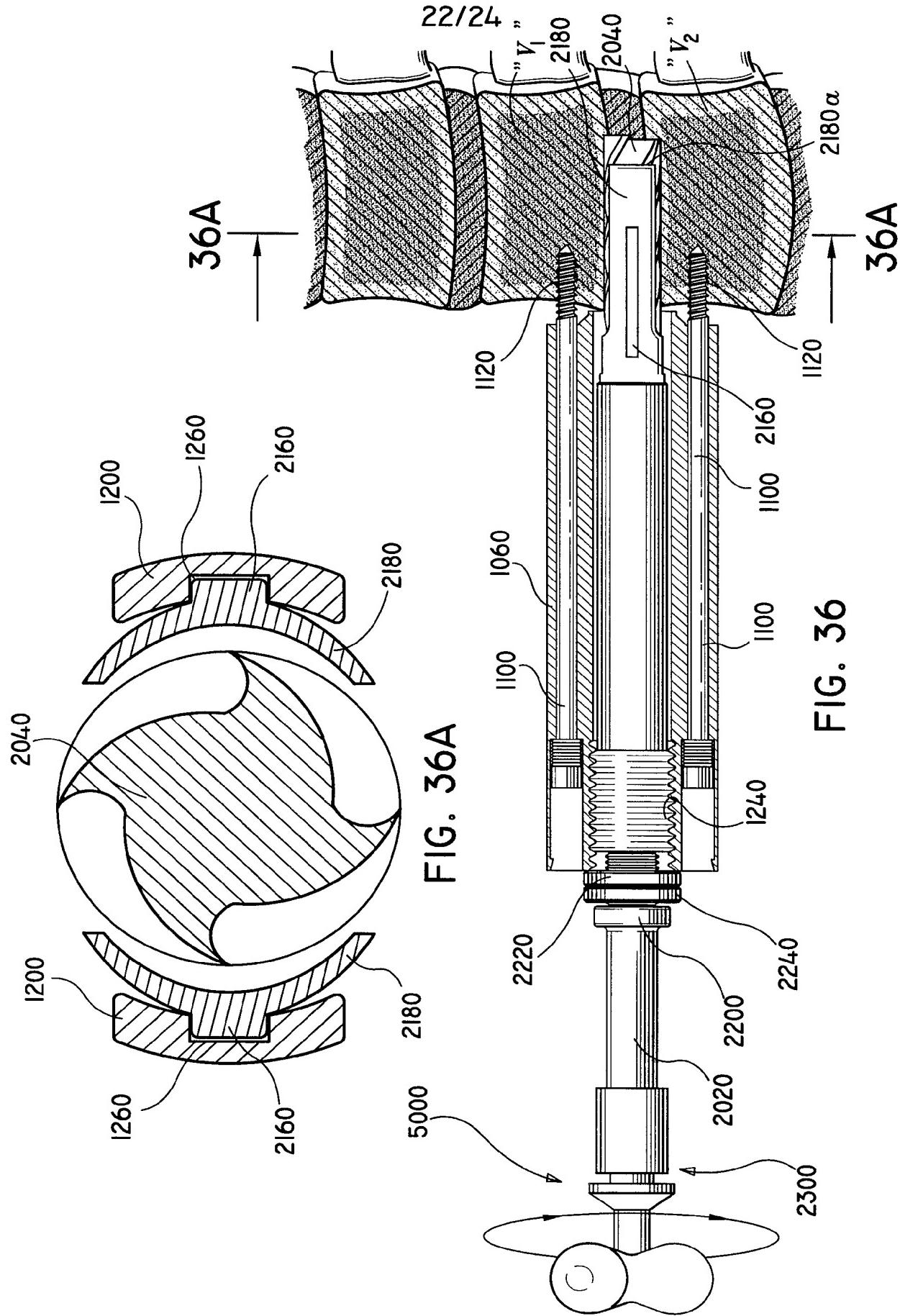
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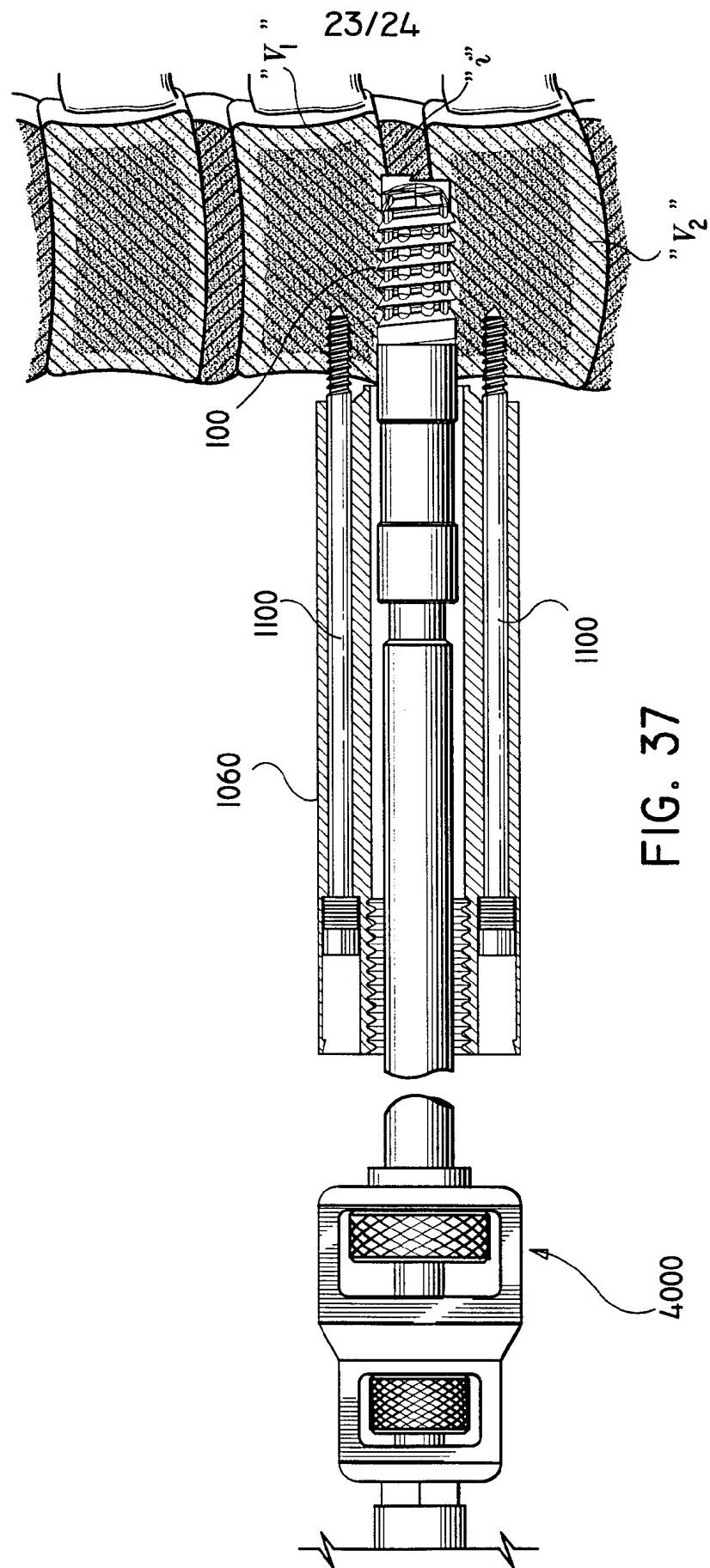






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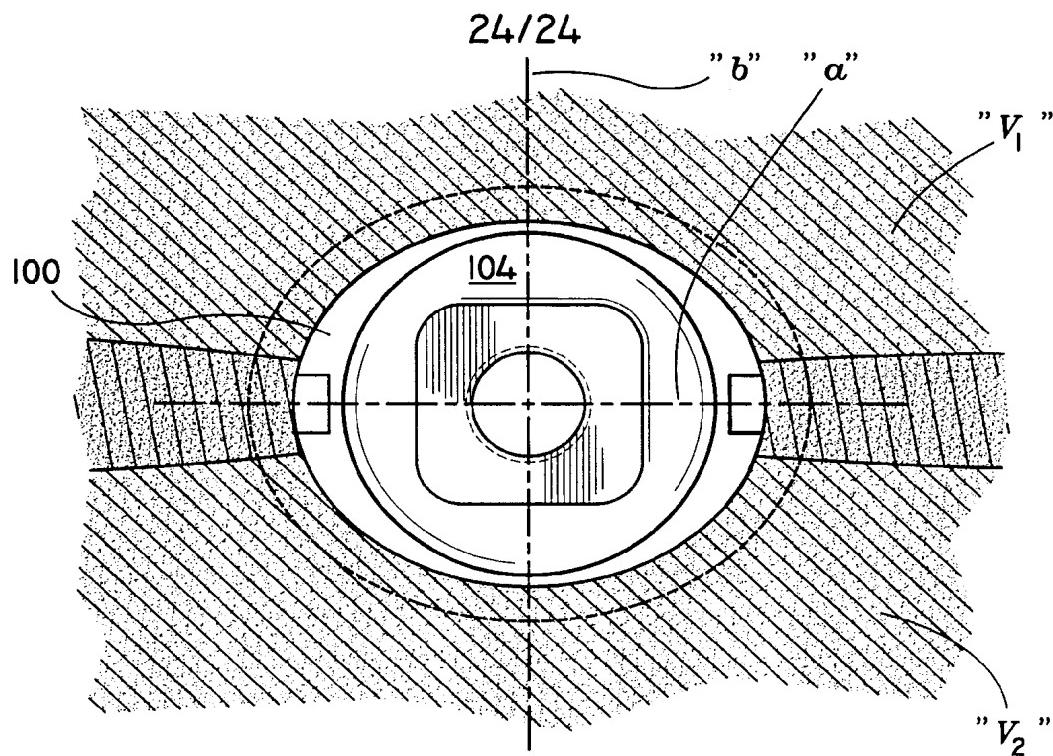


FIG. 38

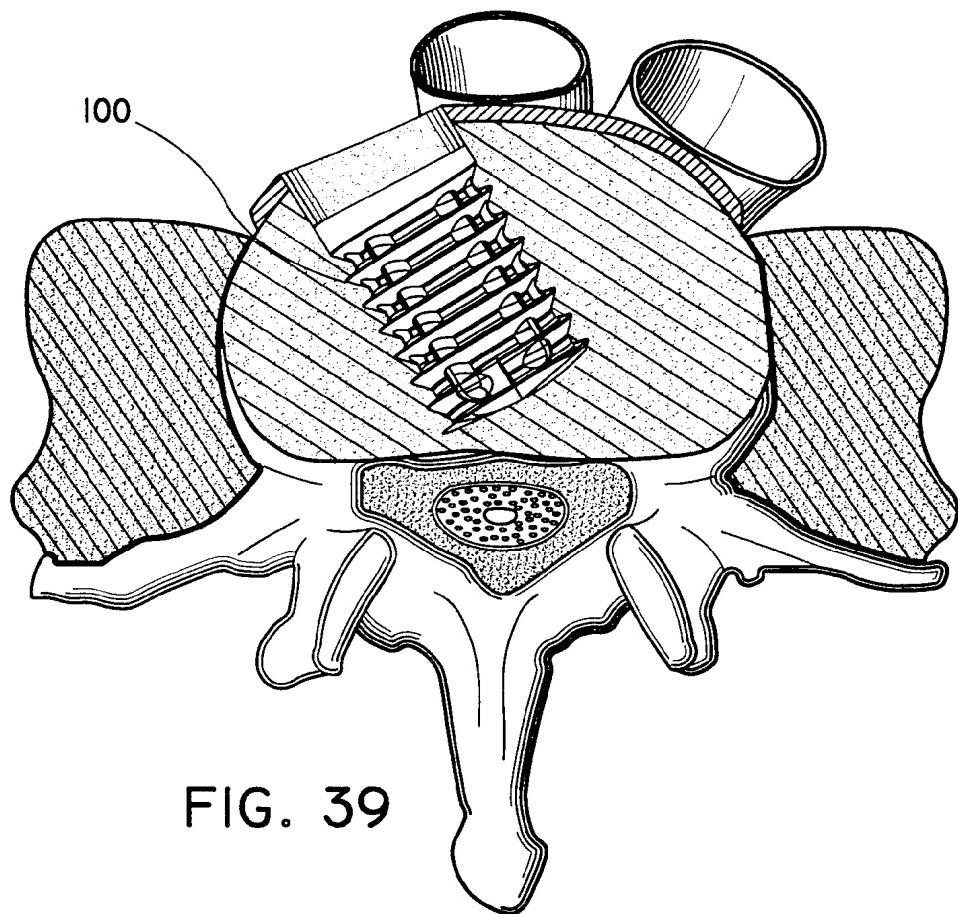


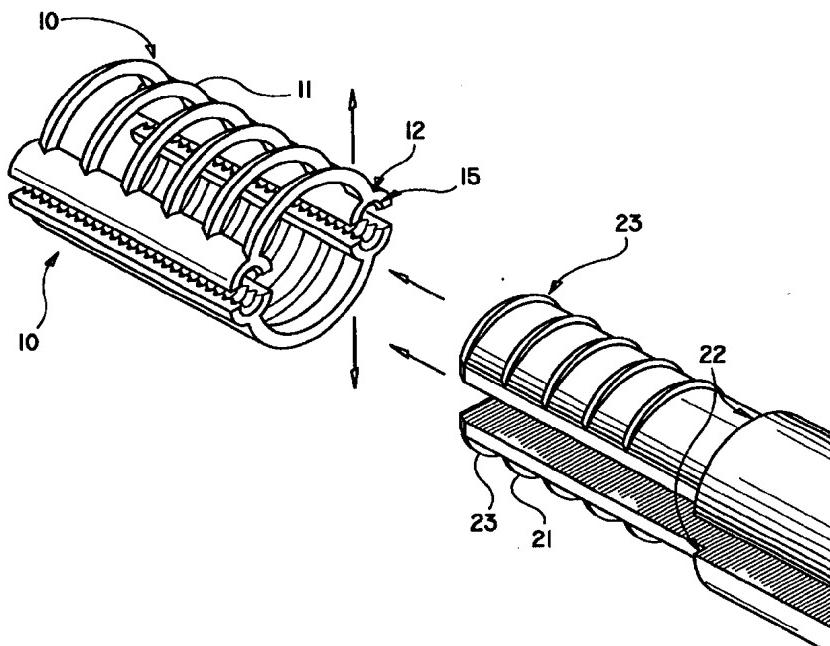
FIG. 39



## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(22) International Filing Date:	6 February 1998 (06.02.98)	(30) Priority Data:	60/037,458 6 February 1997 (06.02.97) US
(71) Applicant (for all designated States except US):	SURGICAL DYNAMICS [US/US]; 111 Glover Avenue, Norwalk, CT 06856 (US).	(72) Inventor; and	Published
(75) Inventor/Applicant (for US only):	RAY, Charles, Dean [US/US]; 125 Alexander Walker, Williamsburg, VA 23185 (US).	(74) Agents:	With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.
(74) Agents: BARRESE, Rocco, S. et al.; Dilworth & Barrese, 333 Earle Ovington Boulevard, Uniondale, NY 11553 (US).			

(54) Title: EXPANDABLE NON-THREADED SPINAL FUSION DEVICE



## (57) Abstract

An apparatus for facilitating the fusion of adjacent bone structures includes implant members (4) configured for insertion within a space defined between adjacent bone structures. The device of the disclosure provides a series of resilient supporting arches (11) which serve to act as spacers between two adjacent bone structures. The implant members (4) include a longitudinal portion separated by a plurality of ribs and a lateral chamber used to accommodate various sized spacer rods (16, 17, 18).

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## EXPANDABLE NON-THREADED SPINAL FUSION DEVICE

### **BACKGROUND**

#### **1. Technical Field**

The present disclosure generally relates to a surgical apparatus and associated methods for fusing two adjacent bone structures such as vertebrae of the spine using an anterior or posterior interbody approach.

#### **2. Background of the Related Art**

The deterioration of a body joint such as an intervertebral disc causes the joint space to undergo degenerative changes including narrowing of the joint space and stiffening of the joint. This degeneration of the joint space may lead to mechanical instability of the joint and become severely painful. When no other alternative treatment suffices to stop the disabling pain the joint may have to be fused together.

The fusion process for intervertebral discs typically requires surgically altering the joint surfaces with removal of the articular cartilage and internal tissues attached to the bone. A mechanical device and/or bone material is inserted into the joint to cause the two formerly moving surfaces to fuse or bridge together via the inserted device or bone. Due to various natural effects, bone fusions grow slowly. As such, the bony union may require a period of several weeks or months of bone ingrowth to have sufficient strength to support normal joint loading. The healing period is of course dependent upon such factors as the patient's age, the location of the joint, the forces applied to the joint and the rate

by which the bony union progresses in the particular patient. A successful fusion demands that the bone structure of the one bony component of the joint grow together with the bone structure of the second bony component of the joint thereby creating a solid union between these two bony components.

5                   All bones are composed of cortical and cancellous portions, the cortical portion being a thin, hard outer shell and the cancellous portion including an internally soft material. It is known that the most successful fusion promoting substance to be inserted between the two joint components is cancellous or soft bone taken as a graft from a donor site within the patient's body. This soft bone  
10                  constitutes an autograft and contains growth promoting substances and biochemical materials which accelerate the rate of growth and quality or solidity of the resultant bone fusion. Further, the bone graft material must be supported and stabilized so that it is not subjected to motion or dislocation. During the growth of the bone fusion, a space less than  $200\mu\text{M}$  between the bone components and the  
15                  fusion material will inhibit good bone growth. However, a space of this size or larger permits the ingrowth of fibrous tissue causing the resulting fusion to be poor in strength or to fail to fuse altogether. Along the same lines, motion within the fusing joint or between the bone graft particles will also inhibit bone growth and subsequently inhibit a secure attachment of the bone graft particles to the joint's  
20                  bony components. In addition, the bone graft material must be brought into contact with a bleeding or vascularized surface of the bone joint to be fused. Since the cancellous inner bone has good intrinsic circulation which is vital to fusion growth, the outer cortical bone must be cut or ground away such that the vascularized cancellous inner bone is exposed and bleeding. It is to this bleeding

or vascularized surface that the bone graft is applied.

Proper bone fusion requires that the bone graft material be held firmly in place within the joint space without any excess movement throughout the fusion process. Many methods and devices have been devised to secure the bone graft firmly in place as well as to secure the bony components of the joint in the desired position as the bony fusion slowly develops. Conventional prior art fusion devices are not suitable for the requirements for which the disclosure has been developed. For example, U.S. Patent No. 4,961,740 to Ray et al. discloses an interbody cage having an internal cavity with an inner surface and an outer surface. A pair of these devices is screwed into parallel round cavities drilled into the adjacent end plates of the vertebral disk bodies. These cavities traverse the end plates of each vertebra penetrating into their cancellous bony vertebral substance. The cavities are then tapped and tight fitting metal cages are screwed into the cavities. The cages hold the bone graft and the vertebral bodies firmly in place. Perforations that face the vertebrae are abundant, up to 70% of the outer surface, but the lateral sides of the cages that face the disc space interposed between the vertebrae are blocked against possible soft tissue ingrowth. Such circular fusion devices must penetrate through the cartilaginous vertebral end plate and into the spongy bone of the vertebral body in order for the bone graft material to grow into the vertebral body and create a solid fusion.

The physical shape, namely the height, of a degenerative vertebral disk is dependent upon its actual state of degeneration. In the less degenerated disc, the diameter of the circular fusion cage must be increased to conform with the disk shape. The maximum diameter of a single cage that can be accepted in a

given disc joint is limited by the space between the facet joint or pedicle, laterally, and the posterior disc midline. Thus, there is a limit to which the cage can effectively span the disc in relation to the disk height required and the disk posterior width available. The fusion device of the disclosure allows for an  
5 increase in height without a resulting concomitant increase in width.

For successful fusion growth development, the recipient bone surfaces must have the cortical or hard surface portion removed. Beneath this hard surface, the cancellous or soft inner portion of the bone, containing its own circulation will then be exposed to the placement of fusion inducing substances  
10 such as cancellous or soft bone from another human (allograft) or from the same patient (autograft). When these fusion inducing substances are first placed within the recipient bone, they have little cohesive strength and therefore are very soft and loosely packed. Therefore, a number of devices and appliances have been developed to hold the bony segments in place under conditions of normal spinal  
15 activity and daily stresses. The bone graft material being placed between these segments will slowly reunite the segments. Such devices are not, by themselves, intended to permanently secure immobility of the segments, since bone ingrowth is required to produce the stable fusion.

Dependency on any non-uniting device as the sole stabilizing  
20 element may ultimately fail due to the development of mechanical transitions between the bone and the device which will lead to a structural failure of the bone.

Fusion bone material placed between vertebral bodies has been described for some years, but more recently the development of pedicle screw fixation and posterolateral instrumentation has become increasingly popular

because of the improvement in percentage fusion rate as compared to the earlier interbody fusion methods. However, the pedicle screw technique has been fraught with a number of problems, particularly related to the patient's safety. Most recently, interbody fusion methods utilizing a bone container, such as a threaded fusion cage, have become increasingly popular because of the improvement in safety and efficacy over other methods and because of lower incidences of complications.

The interbody fusion method is known to be a more efficient technique as compared to methods where bone material is placed around the outside of the vertebral bodies. The interbody fusion is at the center of motion of the spinal segment and requires the least volume of bone to effect a good bone fusion. Further, the fusion enhancing bone material is nearly surrounded by the cortical and/or cancellous bone of the vertebrae which provides good nutrition for the fusion growth. For bone material which is laterally placed, nutrition is usually derived from the under surface of the surrounding muscle which is vascularized during the insertion of the fusion device.

The use of cylindrical interbody fusion devices are simpler and safer to implant than are rectangular bone grafts or fusion enhancing devices. To implant a pair of threaded cylindrical fusion devices by a posterior approach, the disc space is entered via two parallel penetrations, one on either side of the central spinous process. Two holes are then drilled or tapped into the interposed disc space and into the adjacent surfaces of the vertebral bones so as to accommodate the two parallel hollow cages. In the case of implanting a pair of threaded cylindrical fusion devices by an anterior approach, two holes are drilled or tapped

in close proximity. Screw threads are then cut into the recipient bone bed. The screw threads penetrate into each of the vertebral bodies by a distance of about 3 mm which is sufficient to permit direct contact with vascularized cancellous portions of the vertebrae.

5                   The implantation of a pair of fusion devices is important for stability of the joint space but the method for inserting them must abide by certain anatomical limitations. For example, a singular implant of large diameter of more than 18 to 20 mm cannot be implanted by a posterior approach since the nerves cannot be retracted far enough from either side of the midline to permit such a  
10                  large device to be safely inserted. The excessive nerve retraction required could readily lead to a nerve stretch injury with damage to nerve function resulting in postoperative severe pain or partial paralysis. Although a range of diameters of the inserts must be available to accommodate disc spaces of different height, fortunately, it has been found that only two different lengths (21 mm and 26 mm)  
15                  of the implants are needed to accommodate the normal range of vertebral sizes.

                       The height of the disc space determines the diameter of the insert to be implanted. The distance between the pedicles, from side-to-side across the disc space of the vertebral body ranges from about 30 mm to 45 mm in different sized patients. This distance limits the transverse space available to one or more  
20                  implants. However, the entire width between the pedicles cannot be used since the vertebrae are oval shaped and the corners of the implants cannot extend outside the vertebral body oval. To do so would otherwise damage or endanger important nerves or major blood vessels that closely approximate the vertebrae. Thus, the combined diameters of a pair of implant devices cannot be wider than about 6 mm

less than the overall vertebral body width along the disc level. Therefore, the available practical width usable for a pair of cylindrical implants ranges from about 24 mm to 39 mm. Since each cylindrical implant device must penetrate about 3 mm into each vertebral body so as to contact the cancellous portion of the  
5 bone, a disc height equaling or exceeding about 12 mm would require each cylindrical device to be about 18 mm to 20 mm in diameter. However, a pair of such sized devices cannot physically be accepted into a side-to-side arrangement width of the intervertebral disc space. As such, a transversely narrow vertebral segment having a high disc degradation space cannot accommodate two parallel  
10 cylindrical implants. Clearly, an improved implant having the ability to increase vertical height without the associated increase in width is needed in the art.

In order for an interbody fusion device to be stable once implanted within the disc space, it is necessary that the device and its implantation technique stretch the anulus fibrosus, the ligamentous band surrounding the outer portion of  
15 the disc. The effective elastic recoil effect of this tough ligament plus the patient's body weight and paravertebral muscle tone, collectively, apply considerable force from both vertebral bodies through the implanted fusion implant, thereby stabilizing the device within the intervertebral space. Further, a pair of such cylindrical implants parallelly placed into the disc space provides important  
20 segmental stability as the bone fusion grows. This stability must withstand normal lateral flexion-extension and torsional forces applied to the segment. A singular cylindrical implant may provide considerable torsional and flexion-extension stability when implanted parallel to the front-back axis of the disc space, but would not provide adequate stability in lateral side-to-side bending as the segment

would hinge over the implant.

The collapse of an implanted cylinder is prevented by two mechanisms, first, the arc of the cage pressing into the vertebral bone includes a distinct compression strength. Secondly, the greater diameter of the implanted cylindrical fusion device is wider than the hole bored into the two vertebrae, that is, the maximum width of the device lies in the disc space inside the vertebral end plates. Therefore, for such a device to further penetrate into either end plate it must stretch the end plate cortical bone. This portion of the cortical bone is the strongest portion of the vertebral body and resists such stretching forces. In actual clinical applications, the implant cages have penetrated into the vertebral bodies by less than 1 mm. The intactness of the cortical edge of the end plate is therefore important to prevention of the collapse of the vertebrae around the implants. A substantial loss in disc space height would be detrimental to the posterior ancillary structures of the spinal segment including the anulus, facet joints and ligaments.

A spherical, expandable spinal implant is disclosed in U.S. Patent No. 5,059,193 to Kuslich. The Kuslich implant includes deformable ribs which may be expanded outwardly once installed inside the prepared disc space. As a spherical implant, however, it is inherently unstable as was ball bearing type implants disclosed by U. Fernstrom in 1966. The Fernstrom device, intended as an artificial disc, proved to be a non-functional device and most of the several hundred devices implanted had to be later removed.

A spine fusion implant having an oval contour is disclosed in U.S. Patent Nos. 5,458,638 and 5,489,308 to Kuslich et al. The Kuslich et al. implants include slots along its outer periphery towards the vertebral bodies. The side

walls are blocked against invasion of disc material as was described in the literature by Ray. The oval shaped insert requires the drilling of three adjacent holes such that the height is at least twice the width. This concept addressed the same limitations in disc width space versus disc height space as discussed above.

5       The Kuslich et al. implants are not expandable and any potential combination of increased height plus expandability are not disclosed by the Kuslich et al. references.

Furthermore, the Kuslich et al. patents disclose that the semi-cylindrical arcuate ribs are not tapered for the purpose of prevention of expulsion or pullout after insertion into the prepared disc space, but rather to promote ease of insertion without concern for expulsion except as may be provided by the settling of vertebral spongy bone into the slots between the ribs.

10      The expandable non-threaded spinal fusion device of the disclosure overcomes the difficulties described above and affords other features and 15 advantages heretofore not available.

### **SUMMARY**

The device disclosed herein provides a series of resilient supporting arches which act as spacers between the two vertebral bodies, but also permit a simple partial collapse of about 1 mm of soft bone into the spaces between the 20 arches. These arches preferably have parallel slots machined perpendicular to the long access of the implanted device. After insertion of the device, a combination of body weight and muscular contractions applied across the vertebrae and device serve to allow the vertebral bone to descend or sink into the parallel slots of the

device. The vertebral bone will descend or sink across the device to a point that will allow fusion promoting substance, i.e. bone material or any of the well known substitutes such as bone morphologic protein, hydroxyapatite or bone growth factor, placed within the slotted arches to be brought into contact with the bone of the vertebral body. Furthermore, the device can be made in a narrow range of sizes since the two halves of the device are placed into a hole bored between the vertebral bodies and then the halves of the device are forced apart to penetrate into the softer bone of the vertebral spongiosa or cancellous bone. Thus, both the width and height of the devices are separately controlled.

10                 The cortical portion of the juxtaposed end plate of the vertebra is cut away by a drilling process thereby forming the hole which will accommodate the two halves of the slotted cage. An insertion tool or spreading device delivers the two halves of the cage inside the hole and then spreads the two halves apart to force the parallel ribs of the cage into the recipient soft bone.

15                 The spreading device elevates and/or separates the two halves of the cage until the outer anulus of the cage becomes abutted tightly against the receiving bone and capable of exerting sufficient counter force to stabilize each of the slotted cages. While being spread apart by the spreading device, notched rod-like spacers of various heights may then be inserted into the lateral stabilizing structures or channels of each cage. Once the notched spacers are inserted, the spreading device is released and removed from within the two halves of the cage. At this time, the recoil force of the outer anulus of the cage will force the lateral portions of each cage against the spacers further stabilizing them.

In addition, the insertion tool is capable of moving either one of the cage halves further out of or further into the drilled holes of the vertebral body in order to compensate for any slippage between the two vertebral bodies which may have occurred as a result of injury or degeneration. Once the two halves of the cage are situated in the drilled holes of the vertebral body, the insertion tool can then be used to correct the slippage and alignment before the notched spacers are placed. After properly aligning the vertebral bodies, the notched spacers are inserted and positioned along the lateral stabilizer channels of the cage. The insertion or spreading tool is then removed allowing the recoil of the outer anulus of the cage to force the ribs of the slotted arches into the bone, thereby stabilizing the now corrected displacement of the vertebral bodies.

This unique system, therefore, allows for an assortment of diameters of the cages to satisfy a wide variety of heights of the disc spaces. Other objects and advantages of this structure will become apparent from the following detailed description and from the appended drawings in which like numbers have been used to describe like parts throughout the several views.

#### **BRIEF DESCRIPTION OF THE DRAWINGS**

Preferred embodiments of the present disclosure are described herein with reference to the drawings wherein:

FIG. 1 is a view from the posterior aspect of two adjacent vertebral bodies and the fusion implant device of the disclosure;

FIG. 2A is a view from a lateral aspect illustrating two adjacent misaligned vertebrae;

FIG. 2B is a view from a lateral aspect illustrating two correctly aligned vertebrae using the fusion implant device of the disclosure;

FIG. 3A is a cross-sectional view of the slotted two fusion implant halves and lateral stabilizers;

5 FIG. 3B is a cross-sectional view of various sized notched spacer rods;

FIG. 4 is a longitudinal cross-section of the two slotted fusion implant halves and a corresponding spacer rod;

10 FIG. 5 is an exploded isometric view of the slotted fusion implant halves and the insertion-distraction tool;

FIG. 6 is a side planar view of the insertion-distraction tool in the closed position;

FIG. 7 is a side planar view of the insertion-distraction tool in the open position;

15 FIG. 8A is a view illustrating an alternative embodiment of the insertion-distraction tool tip;

FIG. 8B is a view illustrating an alternative embodiment of the insertion-distraction tool tip; and

20 FIG. 9 is a view illustrating the slotted fusion implant halves encasing a core of the bone fusion inducing substance.

**DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS**

The preferred embodiments of the apparatus and methods disclosed herein are discussed in terms of orthopedic spinal fusion procedures and instrumentation. It is envisioned, however, that the disclosure is applicable to a wide variety of procedures including, but, not limited to ligament repair, joint repair or replacement, non-union fractures, facial reconstruction and spinal stabilization. In addition, it is believed that the present method and instrumentation finds application in both open and minimally invasive procedures including endoscopic and arthroscopic procedures wherein access to the surgical site is achieved through a cannula or small incision.

The following discussion includes a description of the spinal fusion implant utilized in performing a spinal fusion followed by a description of the preferred method for spinal fusion in accordance with the present disclosure.

In the discussion which follows, the term "proximal", as is traditional, will refer to the portion of the structure which is closer to the operator, while the term "distal" will refer to the portion which is further from the operator.

Referring now to the drawings in which like reference numerals identify similar or identical elements throughout the several views, FIGS. 3-5 and 9 illustrate, in perspective, the fusion implant device of the disclosure. Fusion implant device 5 is contemplated to be a self-tapping implant, i.e., the implant is intended to be inserted within a preformed bore in adjacent bone structures, e.g., adjacent vertebrae, without necessitating tapping of an internal thread within the bone structures prior to insertion. Fusion implant device 5 is preferably fabricated from a suitable bio-compatible rigid material such as titanium and/or alloys of

titanium, stainless steel, ceramic materials or rigid polymeric materials. It is also contemplated that fusion implant device 5, at least partially, be fabricated of bioabsorbable materials.

With reference to FIG. 1, disk vertebrae 1, 2 and an implanted  
5 fusion implant device 5 according to the disclosure is shown. A posterior aspect  
of the two adjacent vertebral disks 1, 2 include a pair of fusion implants 5  
containing inserted rod-like spacer inserts 16, 17, 18 and bone fusing material 27  
contained therein. The fibers of the ligamentous anulus 3 and the bilateral  
laminectomies are preformed through the posterior bony structures 4 which  
10 surround the fusion implants 5.

As is best depicted in FIGS. 2A and 2B, vertebrae disc 6 is misaligned with respect to vertebrae disc 7 in that disc 6 has slipped forward relative to disc 7. The direction of force necessary to correct the slippage is shown by the opposing arrows near the ligamentous anulus space between the  
15 vertebral discs. With the use of the fusion implant device 5 and methods disclosed in the disclosure, it is possible to correct such misaligned discs as is shown in FIG. 2B. Vertebrae discs 8 and 9 are corrected relative to each other with the use of the fusion implant device 5 and are now in proper anatomical alignment.

With reference to FIGS. 3A and 3B, the fusion implant device 5 includes slotted fusion implant halves 10 and their respective lateral stabilizers 12 to which the arches of the fusion implant device 5 are provided in the form of spaced apart slotted ribs 11. The union of the slotted fusion implant halves 10 form a fusion cage 34, as is shown in FIG. 9. As shown in FIG. 3A, the lateral stabilizers 12 include a semi-circular outer periphery, however, the lateral

stabilizers 12 could also include a less arcuate or horizontal outer periphery thereby allowing the cortical plates to rest upon the lateral stabilizers and further prevent the lateral collapse of the vertebral bodies. Notches 15 line the interior portion of the lateral stabilizer portions 12 along the lateral stabilizer channels 14.

5       The notches 15 of the lateral stabilizers 12 correspondingly engage with notches 20 of the various sized rod spacers 16, 17, 18 when inserted into the lateral stabilizer channels 14. It is to be contemplated that the notches 15 of the lateral stabilizer portions 12 and the notches 20 of the spacers 16, 17, 18 can include like engagement apparatuses such as threads, ribs, teeth or facets. The space 13 between the lateral stabilizer portions 12 is spread apart to accommodate the various heights of spacers 16, 17, 18. In operation, the notches 15 of the lateral stabilizers 12 engage the notches 20 of the spacers 16, 17, 18 and form a single unitary cage 34. The spacers 18 include lateral shoulders 19 which are designed to resist collapse of the fusion implant cage 34 when under a crushing force.

10      After the two implant halves 10 of the fusion implant device 5 have been used to correct the slippage between two vertebrae, the crushing force applied between the notches 15 of the stabilizers 12 and the notches 20 of the spacers 16, 17, 18 will not allow the two vertebra from slipping back into the original misaligned or abnormal position. The spacer inserts 16, 17, 18, as well as the fusion implant halves 10 may also be made of a bioabsorbable material so that they will slowly dissolve as the bone fusion between the two vertebral bodies continues to grow. In doing so, the spacer inserts 16, 17, 18 will slowly transfer the forces resisting collapse back to the resulting bone graft or fusion. Thus, as the bone graft or fusion continues to grow, it will gradually take over the load forces and thereby

enhance the growth and overall strength of the resultant graft or fusion.

As is best depicted in FIG. 4, the mating relationship between the spacer 16 and the two fusion implant halves 10 is shown. The two fusion implant halves 10 include ribs 11 having sloped surfaces 30 designed to prevent expulsion or pullout of the fusion implant halves 10 under force. The sloped surfaces 30 of the ribs 11 may vary in degree to a slope which is dependent upon the amount of force expected to act upon the inserted fusion device 5. Once chosen for appropriate height, spacer 16 showing notches 20 is inserted into the space 13 between the lateral stabilizer portions 12. Spacer 16 including notches 20 will 10 then be matingly fitted with the notches 15 of the lateral stabilizer portions 12.

With reference to FIGS. 5-7, insertion-distraction tool 21 is designed to accommodate the various potential lengths of fusion implant halves 10. Insertion-distraction tool 21 includes limit stops 22 which prevents tool 21 from being over inserted into the fusion implant halves 10. The tool 21 includes lateral 15 retaining ribs 23 which are designed to grab the internal portions of slotted ribs 11 of fusion implant halves 10. The lateral retaining ribs 23 allow for the insertion-distraction tool 21 to be displaced relative to each other in order to permit realignment of slippage of one vertebra disc relative to another vertebrae disc.

The insertion-distraction tool 21, as shown in FIG. 6, includes 20 handles 25 which are normally displaced apart from one another when the insertion-distraction tool 21 is in a resting or spread apart position. In this resting position, the tool tips 24 are positioned closed so that the tool 21 may be inserted within the fusion device halves 10. In operation, tool tips 24 are inserted within the fusion device halves 10 until limit stops 22 abut against a proximal slotted rib

11. The central hinge point 26 of tool 21 defines the motion of the handles 25 moving extension mass 29 of the tips 24 around hinge points 27 which causes spreading apart or closing of the tips 24. Two cross members 28 articulate with extension masses 20 to maintain tips 24 parallel with respect to one another when  
5 being spread apart by the actuation of handles 25.

The insertion-distraction tool 21, as shown in FIG. 7, includes handles 25 which are in a closed position and tips 24 which are spread apart in a parallel relationship. In this position, the tips 24 are used to spread the fusion implant halves 10 in a manner parallel to the cortical end plates of the vertebral bodies. A means to shift the location (not shown) of the hinge point 26 would allow the tips 24 to open in a slightly non-parallel fashion as may be needed for the final positioning of the fusion implant halves 10. A ratchet locking means (not shown) to hold the handles 25 in the desired position can be provided to maintain the spreading of the vertebral disc space as the fusion implant halves 10 are  
10 positioned.  
15

With reference to FIGS. 8A and 8B, alternate embodiments of the insertion-distraction tool 21 are shown. A single pair of broad tips 31 can be used to spread the central core of the fusion implant halves 10 into the vertebral bone. In an alternative embodiment, a dual pair of narrower tips or blades 32 can be  
20 used within the lateral stabilizer channels 14 to spread the fusion implant halves  
10. The blades 32 include a central bow 33 which are designed to permit the passage of a central core preform of fusion inducing substance 27.

A pair of slotted fusion implant halves 10 including supporting ribs 11 and lateral stabilizer shoulders 12 are shown in FIG. 9. The insertion-

distraction tool 21 with paired tips 24 or 31 or 32, as discussed above, engages the notches 15 of the lateral stabilizers 12 on both sides of the fusion implant halves 10 spreading them apart to permit the insertion of a preformed porous solid core of fusion inducing substance 27. The porous core 27 may be preformed so that 5 semicircular ridges on the external periphery of the porous core 27 project into and out of corresponding slots 28 between the ribs 11 of the fusion implant halves 10. The porous core 27 is of sufficient strength to withstand the compressive forces between the vertebral bodies as the fusion of the bones develops. Porous cores 27 of various sizes are used to accommodate various disc heights. A 10 temporary spacer porous core (acting simply as a spacer) may be initially placed on one side of the vertebral bodies for partial spreading of the disc space. The second vertebral side will then receive a full height porous core 27. Finally, returning to the first side of the vertebral bodies, the temporary spacer porous core 15 is removed and a permanent porous core 27 is placed within the disc space between the fusion implant halves 10. For further stabilization, if needed, appropriately shaped rods, screws or other similar spacing-type apparatuses may be driven into the lateral stabilizer channels 14 and driven along the length of the stabilizers 12 to add the needed stabilization throughout the implant procedure.

A preferred embodiment of the present fusion implant system 20 includes a slotted fusion implant device 5 to be implanted in and promote fusion with respect to one or more bone structures wherein the fusion implant system contains a bone fusion inducing substance 27, such as bone material, bone morphologic protein, hydroxyapatite or bone growth factor, packed therein. Preferably, the fusion implant system includes a fusion implant having two halves

10 consisting of slotted arches or ribs 11 having an outside radius and an inside radius with deep complete perforations between the arches 11 where the outer portion and inner portion of the arches 11 become confluent. The fusion implant system also includes lateral notched spacer rods 16, 17, 18 having a semi-circular outer periphery that attach along the longitudinal axis of the lateral stabilizers 12 providing a base for them. Also, dependent on the shape of the corresponding lateral stabilizers 12, the spacer rods 16, 17, 18 could include a less arcuate or horizontal outer periphery. The lateral stabilizers 12 have threads or notches 15 along their internal diameters extending along the length of the fusion implant 5.

10 As shown in Figure 4, the circular ribs 11 have slopes of 30 degrees to 45 degrees relative to the longitudinal axis of the fusion implant 5 providing additional resistance to axial displacement or expulsion of the fusion implant halves 10.

Upon placement of both fusion implant halves 10 opposite to each other within a bore drilled between two vertebral bodies, the fusion implant halves 15 10 may be forced apart so that the circular ribs 11 are forced into the softer cancellous bone of the vertebral bodies, thus stabilizing the fusion implant halves 10 within each opposing vertebral body. Lateral stabilizers 12 containing threads or notches 15 are used to accommodate notched rod spacers 16, 17, 18 of various heights that are placed after the fusion implant halves 10 are forced apart in order 20 to maintain the new distracted height of the vertebral bodies after the fusion implant halves 10 have been implanted.

The internal cavity of the two fusion implant halves 10 will accommodate a fusion growth inducing substance 27 either as a preformed core or as separate morsels and protect that substance from extrusion or collapse by the

semi-circular ribs 11 of the fusion implant halves 10. Once the fusion implant halves 10 have been fully distracted and the semi-circular ribs 11 have penetrated into the vertebral bodies, notched spacer rods 16, 17, 18 are placed laterally along the lateral stabilizers 12 wherein the notches 20 of spacers 16, 17, 18 engage the notches 15 of the lateral stabilizers 12, thus holding the fusion implant halves 10 firmly apart and preventing axial displacement of the two halves 10 relative to each other's position.

The fusion implant system is installed with an insertion-distraction tool 21 capable of separating the two fusion implant halves 10 to the appropriate distraction which allow for the placement of spacers 16, 17, 18 before removal of the tool. The tool 21 preferably has two halves, as shown in Figure 5, with each half having notches or prominences 23 around their diameter that engage the internal rib structure 11 of the fusion implant halves 10 to prevent their displacement relative to the tool 21. The two halves of the insertion-distraction tool 21 may be axially displaced relative to each other in order to move the position of the fusion implant halves 10 and thereby the now attached vertebral bodies for the purpose of realignment of a displacement of the two vertebral bodies relative to each other. The tool 21 includes jack-like scissor linkage, as described earlier, to keep the jaw-like tool halves and tips 24 generally parallel.

The fusion implant system of the present disclosure, therefore, has the novel ability to adapt to varying vertebral bodies as to the softness of their bone, width of the disc space and then to allow sufficient corrective force to permit realignment of the pathologically displaced vertebra.

In operation, the novel fusion implant system can be implanted by the following method using a standard surgical approach as though a laminectomy or discectomy is to be performed on either side of the vertebral body. Prior to the act of drilling bore holes into the vertebral bodies, the nerve structures are

5 displaced first to one side and then to the other side in order to avoid contact with the intervertebral drill. Two bore holes are drilled to the appropriate depth, extending at least 75% of the total intradiscal front to back diameter. The bore holes should penetrate through the end plates bilaterally and be between 1 to 3 mm in depth into the cancellous portion of the vertebral bodies. The bore holes would

10 normally be between 10-14 mm in diameter. The two arched halves 10 of the fusion implant device 5 are then mounted on the insertion-distraction tool 21 and inserted into one of the drilled holes. One drill hole is fitted with the fusion implant device 5 and then the other drill hole is similarly fitted. The insertion-distraction tool 21 seats the fusion implant device 5 deeply within the hole to a

15 point where the tool 21 abuts against the posterior margin of the hole, as determined by the limit stops 22 which are machined on the tool 21. Distraction of the tool 21 then forces the sloped surfaces or sharpened edges 30 of the ribs 11 of the implant halves 10 deeply into the cancellous bone. Further, the distraction tool 21 spreads the space until the anulus of the fusion implant device 5 is quite

20 firmly seated and within normal intervertebral distance. Appropriate elongated spacers 16, 17, 18 are then inserted into the space 13 between the lateral stabilizers 12 engaging small notches 15 within the lateral channels 14 to prevent slippage of one fusion implant half 10 relative to the other along the common axis of penetration. The height of the spacers 16, 17, 18 is chosen to provide

sufficient firmness to the anulus where a counter force will then hold the fusion implant halves 10 and its lateral spacers 16, 17, 18 in firm axial alignment relative to each other. The tool 21 is then released and removed allowing the full outer anulus force to be exerted against the fusion implant halves 10 and the spacers 16, 5 17, 18. The cage 34 is then packed with an appropriate amount of bone fusion inducing substance 27 such as an autograft or allograft. A ceramic insert may be fitted for the cage 34 or small portions of hydroxylapatite may be packed inside the cage 34. This packing of the fusion inducing material 27 further provides strength so as to resist the potential collapse of the cage 34 or the over penetration 10 of the slotted ribs 11 into the recipient bone bed.

An additional method for the surgical procedure would best be used on patient's having a degenerative or traumatic slippage of one vertebra upon the other. In this case, the procedure would be different, in that, after the elevation or spreading of the implant halves 10, one portion of the insertion tool 21 would 15 then slide inward or outward relative to the other implant half 10 and insertion tool 21 so that the bone into which the implant half 10 has been inserted may be realigned relative to each other along their anterior-posterior axes. Once repositioned, the system should be sufficiently stable to resist re-slippage or misalignment after the tool 21 has been removed. This procedure may require that 20 one implant half 10 be inserted deeper relative to the other before the realignment process begins. After spreading the space and forcing the implant halves 10 into the recipient bone beds the halves 10 and the attached vertebral bodies would be appropriately repositioned. This corrected position would be secured by effectively locking the notched portions 15 of the lateral stabilizers 12 into the

notched portions 20 of spacer rods 16, 17, 18. The notches 20 the spacer rods 16, 17, 18 would be forced tightly into the corresponding notches 15 of the lateral stabilizers 12 by the forces of the anulus recoil and body weight of the patient. These forces would prevent the now corrected vertebral alignment from any further slippage.

5 A further method uses a spreader means to elevate the two sides of a semicircular fusion insert half 10 by its transverse slots 28 such that a suitable fusion core insert 27 may be installed inside the central core of the fusion implant cage 34. This method provides that the lateral slots 28 be elevated while a central 10 core insert 27 of correct height is placed within the fusion implant halves 10. This core insert 27 should be made of a porous bone growth inducing substance to create a fusion between the core substance and the vertebral body bone beds which are apparent across the slots 28. This method may use a preformed core 27 of sufficient strength to support the vertebral load during fusion development. This 15 current method is in contrast with the previously discussed method which requires the packing of morsels of fusion inducing substance 27 after the fusion implant device 5 is placed within the vertebral bodies. Lateral transverse notched spacer rods 16, 17, 18 may additionally be placed if further stability is needed. The preformed insert 27 may have mating grooves to fit within the slots 28 of the 20 fusion implant 5 to partially fill the slots 28 and provide additional anterior-posterior resistance to slippage (spondylolisthesis). When a preformed core 27 is used having semicircular elevations to match the fusion insert slots 28; the implant halves 10 may be independently repositioned using the appropriate insertion-distraction tool 21 to correct any slippage. The mated elevations and grooves of

the preformed core 27 then serve as a means to prevent a return to the slipped or misaligned position.

In operation, the alternative embodiments and methods of the fusion implant system can be implanted by the following method using a standard surgical approach as though a laminectomy or discectomy is to be performed on either side of the vertebral body. Prior to the act of drilling bore holes into the vertebral bodies, the nerve structures are displaced first to one side and then to the other side in order to avoid contact with the intervertebral drill. Two bore holes are drilled to the appropriate depth, extending at least 75% of the total intradiscal front to back diameter. The bore holes should penetrate through the end plates bilaterally and be between 1 to 3 mm in depth into the cancellous portion of the vertebral bodies. The bore holes would normally be between 10-14 mm in diameter. The lateral slots 28 of the two arched halves 10 of the fusion implant device 5 are then mounted on the insertion-distraction tool 21 and inserted into one of the drilled holes. One drill hole is fitted with the fusion implant device 5 and then the other drill hole is similarly fitted. The insertion-distraction tool 21 seats the fusion implant device 5 deeply within the hole to a point where the tool 21 abuts against the posterior margin of the hole, as determined by the limit stops 22 which are machined on the tool 21. Distraction of the tool 21 then forces the sloped surfaces or sharpened edges 30 of the ribs 11 of the implant halves 10 deeply into the cancellous bone. Further, the distraction tool 21 spreads the space until the anulus of the fusion implant device 5 is quite firmly seated and within normal intervertebral distance. A preformed core 27 of appropriate size is then inserted into the central cavity of the fusion implant device 5. This core exerts

force against the ribs 11 of the slotted fusion insert halves 10 which in turn force the ribs 11 into the vertebral bone bed. The correct height of the core provides sufficient firmness to the anulus where a counter force will then hold the fusion implant halves 10 in firm axial alignment relative to each other. The tool 21 is  
5 then released and removed allowing the full outer anulus force to be exerted against the fusion implant halves 10 and the preformed core 27.

When the relationship between the two adjacent vertebral bodies is considerably altered, any of the procedures above may be performed incrementally. That is, part of the needed correction or realignment may be  
10 performed temporarily on one side with the placement of an intermediate sized spreading or correcting insert. That first side with its intermediate correction is then temporarily abandoned while a fully correcting insert is permanently placed on the second side. Then, returning again to the first side, the temporary partial correcting insert is removed and replaced with a permanent insert equal to the one  
15 on the second side, thereby fully correcting or realigning the two vertebrae. Effectively, this method permits a more gradual change in the misalignment which at times may be necessary as the collagen fibers of the ligamentous anulus of the disc sometimes stretch slowly and an initial attempt at full correction on only the first side may cause tearing of these fibers or fracture of the vertebral bone.

20 It will be understood that various modifications may be made to the embodiments disclosed herein. For example, the fusion implant device may incorporate more than two fusion implant sections within a single bore or the external ribs may include a pointed edge with a slope greater than 45 degrees.

Therefore, the above description should not be construed as limiting, but merely as exemplifications of preferred embodiments. Those skilled in the art will envision other modifications within the scope and spirit of the claims appended hereto.

**WHAT IS CLAIMED IS:**

1. A fusion implant system for promoting fusion of adjacent bone structures wherein the fusion implant system contains a bone fusion inducing substance packed therein, the fusion implant system comprising a fusion implant having at least two sections, each section including arches and at least two lateral stabilizers having a longitudinal axis transverse to the arches.  
5
2. The fusion implant system according to claim 1, wherein the lateral stabilizers include channels along the longitudinal axis and the arches include slots.
3. The fusion implant system according to any one of claims 1 or 2,  
10 further including at least one spacer to be matingly received within the channels of each lateral stabilizer.
4. The fusion implant system according to claim 3, wherein the at least one spacer includes a set of various sized spacers for varying a distance between the at least two sections.  
15
5. The fusion implant system according to any one of claims 3 or 4, wherein the at least one spacer further includes engagement apparatus along its transverse outer periphery.

6. The fusion implant system according to claim 5, wherein the channels further include engagement apparatus along their transverse inner periphery.

7. The fusion implant system according to claim 6, wherein the  
5 engagement apparatus of both the channels and the spacers engage each other when the fusion implant system is implemented.

8. The fusion implant system according to any one of claims 1-7, wherein the system is made at least partially from a bio-absorbable material.

9. The fusion implant system according to any one of claims 1-8,  
10 wherein the fusion implant is placed within a hole drilled between the two adjacent bone structures and wherein the fusion implant is pressed against surrounding walls of the hole so that the arches are pressed into the surrounding walls of the hole.

10. The fusion implant system according to claim 9, wherein the at least  
15 one spacer is interposed within the channels of the lateral stabilizers, wherein the spacers are chosen to correspond to a particular height between the fusion implant pressed against the walls of the hole.

11. A method for fusion of adjacent vertebrae having a disk space therebetween, the method comprising the steps:
- accessing the disk space and forming a bore therein;
- implanting a fusion implant device within the bore, the fusion
- 5 implant device including at least two sections, each section including arches and at least two lateral stabilizers having a longitudinal axis transverse to the arches, each lateral stabilizer having a channel along the longitudinal axis;
- positioning the at least two sections of the fusion implant within the bore so that the arches penetrate the bone material of the adjacent vertebrae and
- 10 defining a core area therebetween; and
- inserting a spacer along the channel of each lateral stabilizer.
12. The method according to claim 11 wherein the step of positioning includes:
- inserting an insertion tool within the bore, the insertion tool
- 15 including a handle and a tip structure, the tip structure being received within the bore; and
- expanding the tip structure within the bore against the at least two sections of the fusion implant thereby forcing the arches into adjacent bone material.
- 20 13. The method according to any one of claims 11 or 12, further comprising the step of packing the core area with fusion promoting material.

14. The method according to any one of claims 11-13, wherein the channels of the lateral stabilizers and the spacers include mating apparatus to thereby enhance engagement of the lateral stabilizers and the spacers during the inserting step.

5 15. The method according to any one of claims 11-14, wherein the spacer further includes a set of various sized spacers for varying a distance between the at least two sections.

10 16. A nonthreaded fusion implant system to be implanted in and promote fusion within one or more bone structures, wherein the fusion implant system contains a bone fusion inducing substance packed therein, the fusion implant system comprising:

a fusion implant comprising two halves, each half including arches having an outside portion and an inside portion, wherein the outside portion and the inside portion meet at a confluent edge;

15 lateral stabilizers positioned along a longitudinal axis of each fusion implant half, the lateral stabilizers having notches or threads along an internal periphery along the longitudinal axis;

slotted spacers positioned along the longitudinal axis of the lateral stabilizers; and wherein the confluent edges of the arches include a slope between 20 30 and 45 degrees relative to the longitudinal axis of the fusion implant halves.

17. The nonthreaded fusion implant system according to claim 16, wherein the halves of the fusion implant are positioned within a bore within the bone structures and wherein the halves are forced apart so that the arches are pressed into soft surrounding bone of the bone structures.

5

18. The nonthreaded fusion implant system according to claim 17, further comprising notches or threads along a portion of the outer periphery of the slotted spacers, and wherein the slotted spacers are positioned within the lateral stabilizers to maintain a desired distracted and axial position between the fusion implant halves.

10

19. The nonthreaded fusion implant system according to claim 18, further comprising a protective cavity formed between the fusion implant halves once in the distracted and axial positions, wherein the bone fusion growth inducing substance is placed within the protective cavity.

15

20. The nonthreaded fusion implant system according to claim 18, further comprising an insertion tool having a tip section which is capable of the forcing apart of the fusion implant halves so that the slotted spacers may be positioned within the lateral stabilizers.

21. The nonthreaded fusion implant system according to claim 20,  
wherein the tip of the insertion tool further includes notches to engage the fusion  
implant halves between the arches to thereby prevent the fusion implant halves  
from being displaced with respect to the insertion tool during the positioning of the  
5 fusion implant halves within the bore.

22. The nonthreaded fusion implant system according to claim 20,  
wherein the tip section of the insertion tool further includes dual tips separated  
along a longitudinal axis of the insertion tool, wherein each tip can be axially  
displaced relative to each other along the longitudinal axis of the insertion tool.

10 23. The nonthreaded fusion implant system according to claim 20,  
wherein the tip section of the insertion tool further includes separate blade sections  
to be inserted along the longitudinal axis of each lateral stabilizer, the separate  
blade sections forming a bow section therebetween capable of allowing the bone  
fusion growth inducing substance to be inserted through the bow section.

15 24. The nonthreaded fusion implant system according to claim 16,  
wherein the bone fusion growth inducing substance is a force bearing porous  
preformed core insert.

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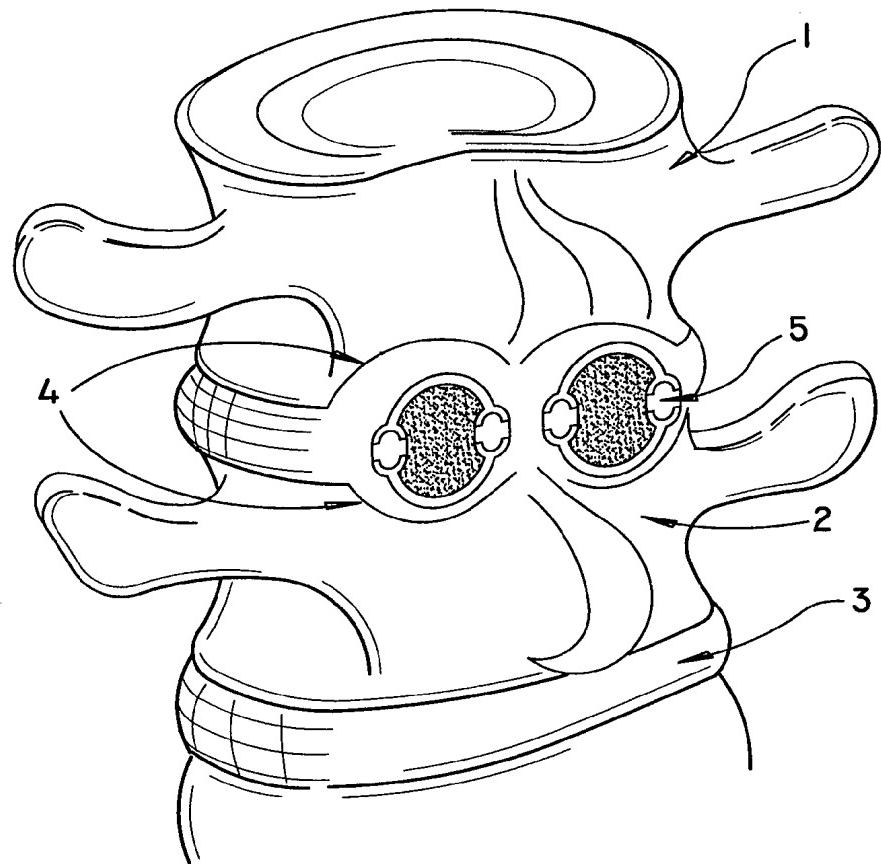


FIG. 1

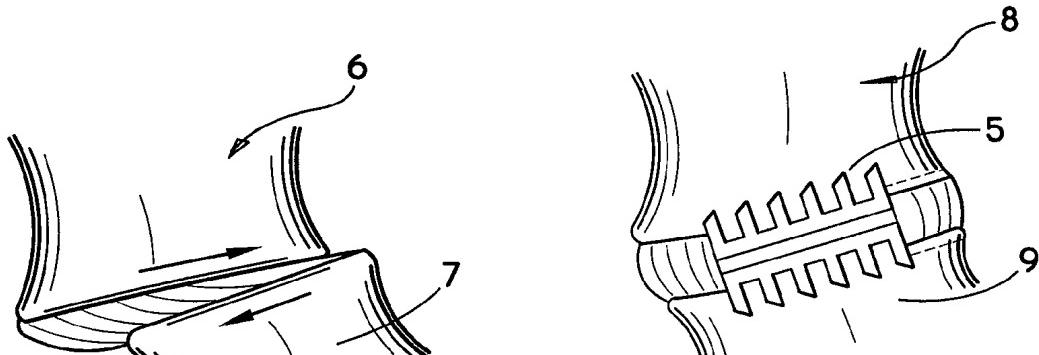
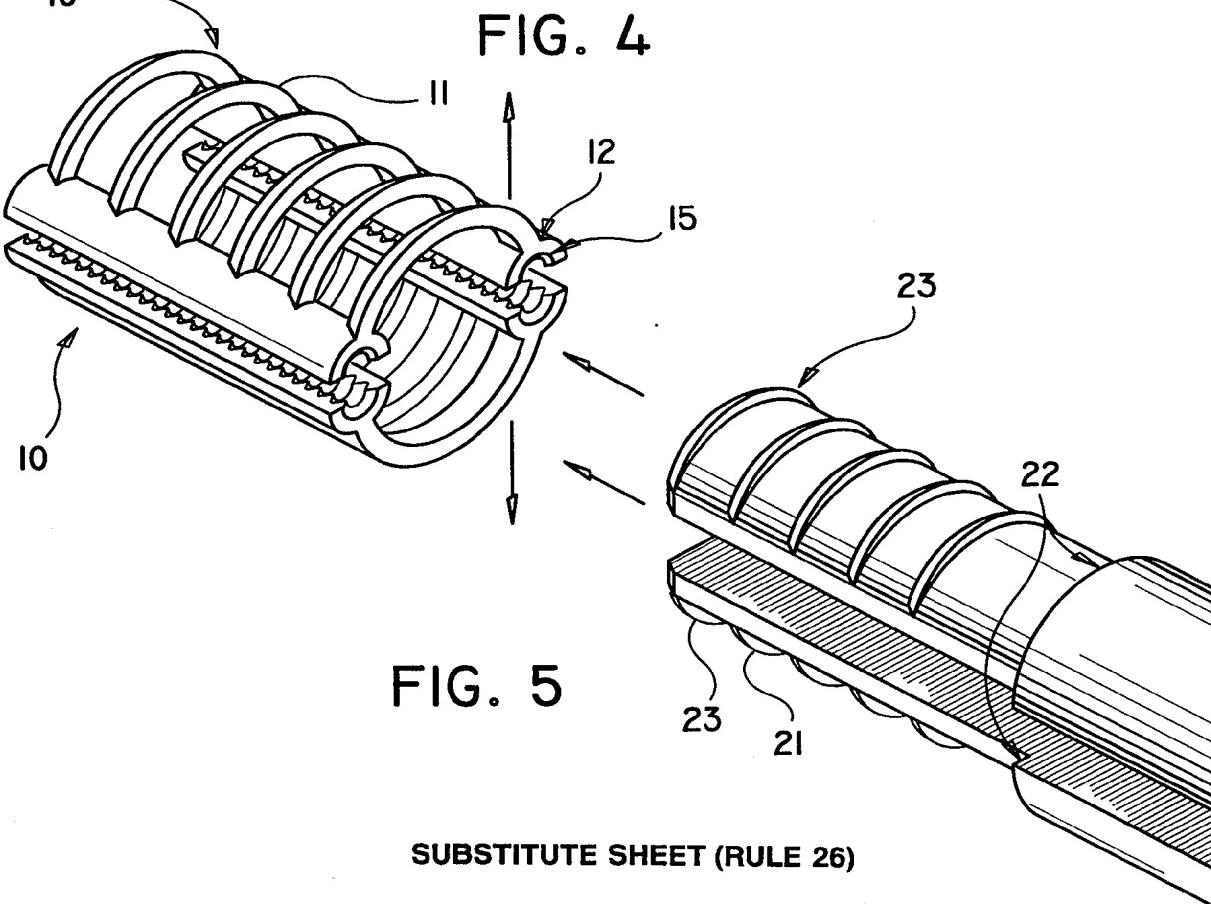
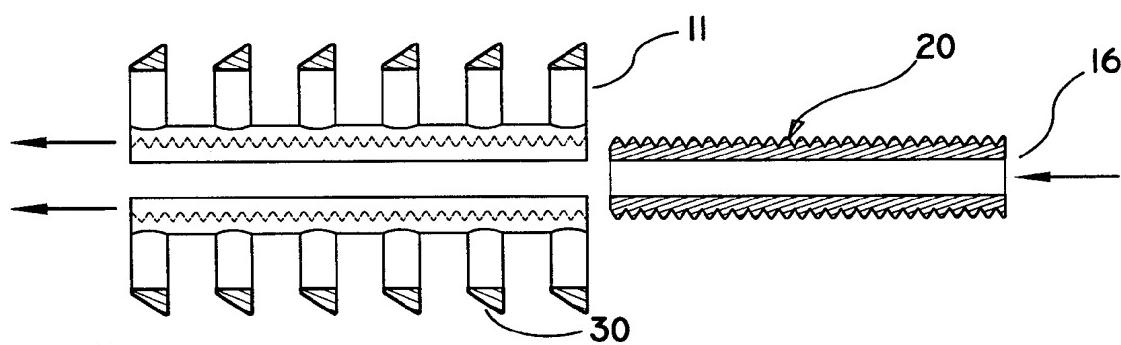
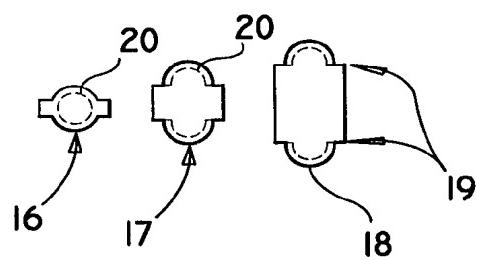
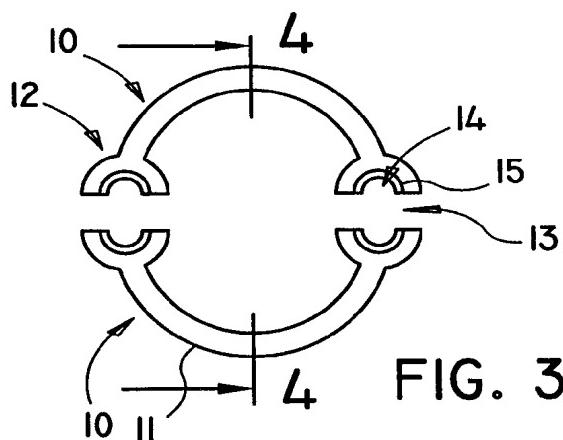


FIG. 2A

FIG. 2B

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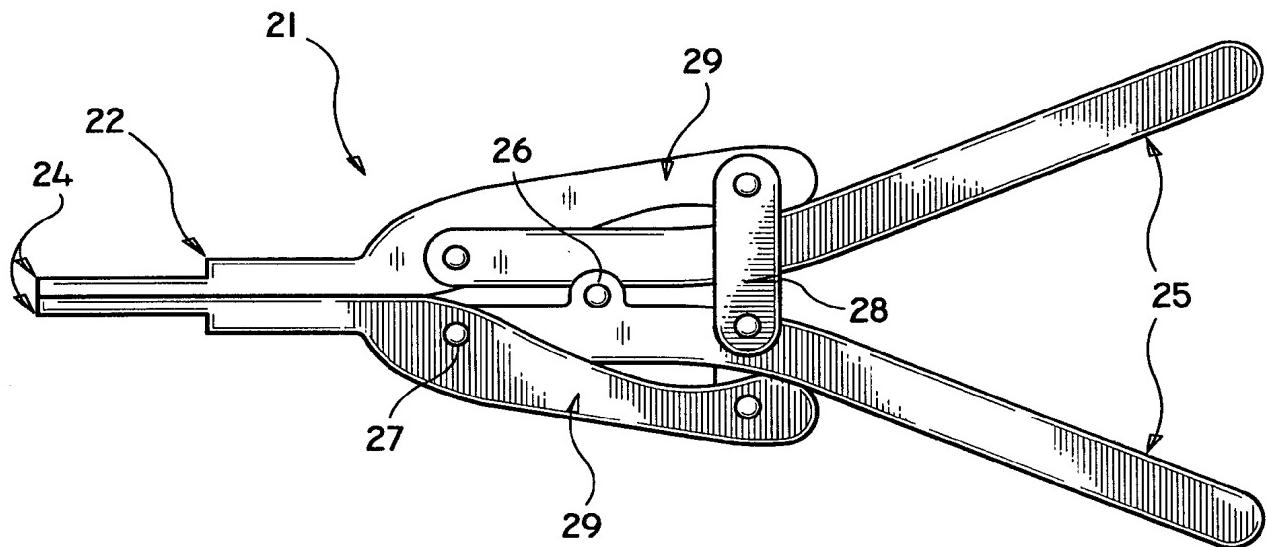


FIG. 6

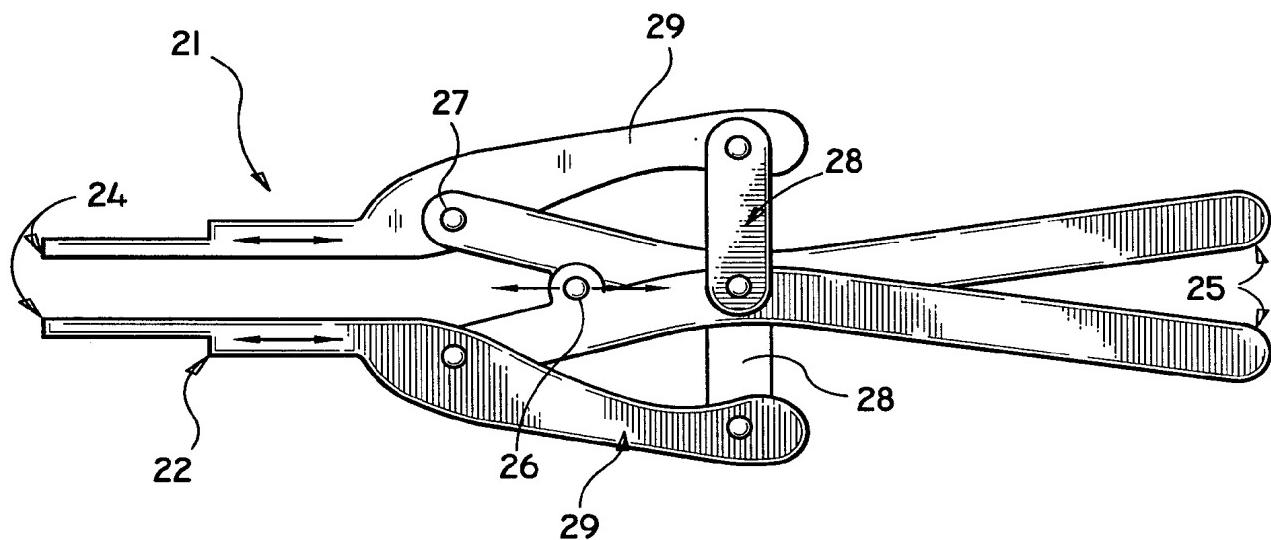


FIG. 7

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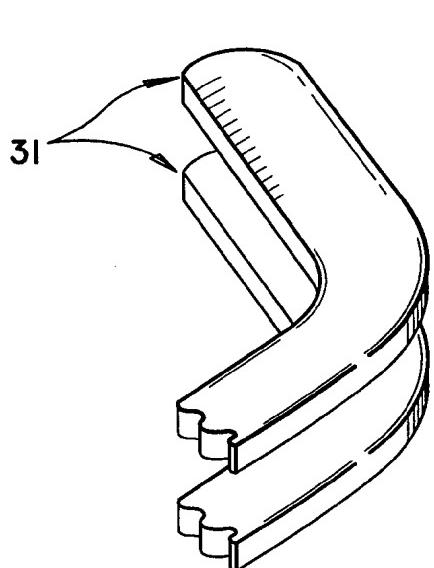


FIG. 8A

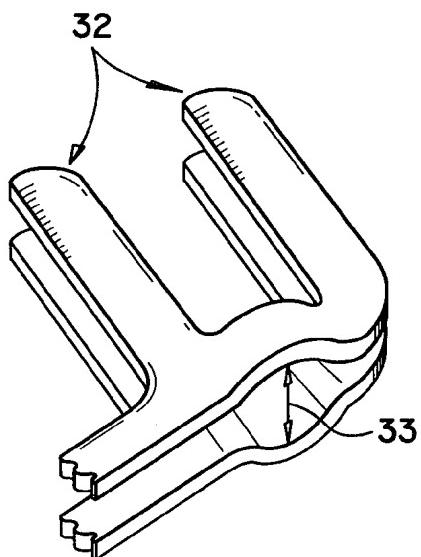


FIG. 8B

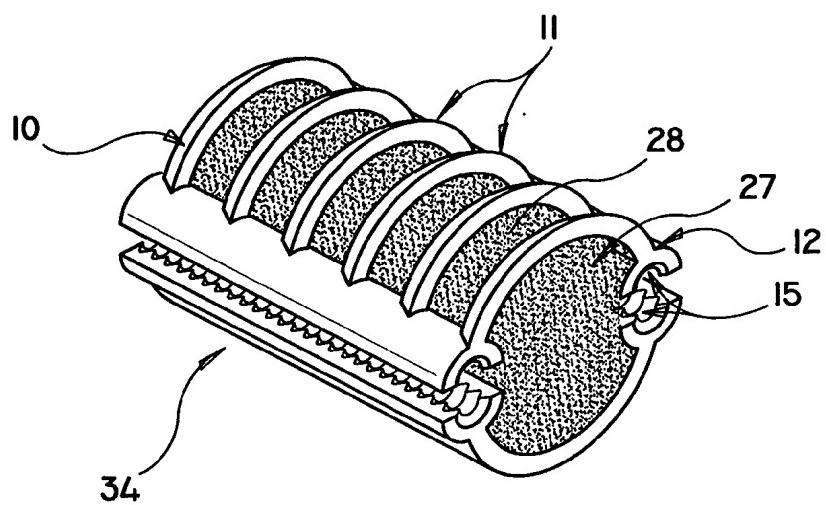


FIG. 9

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US98/02148

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61B 17/70

US CL : 606/61

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/61, 60, 72, 73; 623/17

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

none

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

none

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X, P	US 5,609,636 A (KOHRS ET AL.) 11 MARCH 1997, SEE ENTIRE REFERENCE.	1

 Further documents are listed in the continuation of Box C. See patent family annex.

* Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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Date of the actual completion of the international search

19 JUNE 1998

Date of mailing of the international search report

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**INTERNATIONAL SEARCH REPORT**

International application No.

PCT/US98/02148

**Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)**

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1.  Claims Nos.: because they relate to subject matter not required to be searched by this Authority, namely:
  
2.  Claims Nos.: because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
  
3.  Claims Nos.: 5, 8-10, 14,15 because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

1.  As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2.  As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3.  As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
  
4.  No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

**Remark on Protest**  

The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.

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INTERNATIONALE ANMELDUNG VERÖFFENTLICHT NACH DEM VERTRAG ÜBER DIE  
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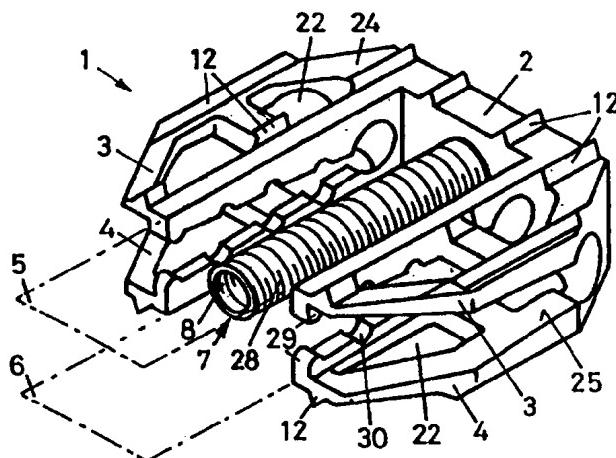
(21) Internationales Aktenzeichen: PCT/CH97/00293	(81) Bestimmungsstaaten: AU, BR, CA, CN, JP, MX, NO, US, europäisches Patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).
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(71) Anmelder ( <i>für alle Bestimmungsstaaten ausser US</i> ): SYNTHES AG CHUR [CH/CH]; Grabenstrasse 15, CH-7002 Chur (CH).	<b>Veröffentlicht</b> <i>Mit internationalem Recherchenbericht.</i>
(71) Anmelder ( <i>nur für CA</i> ): SYNTHES (U.S.A.) [US/US]; 1690 Russel Road, P.O. Box 1766, Paoli, PA 19301-1222 (US).	
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(74) Anwalt: LUSUARDI, Werther; Dr. Lusuardi AG, Kreuzbühlstrasse 8, CH-8008 Zürich (CH).	

(54) Title: INTERVERTEBRAL IMPLANT WHEREOF THE PARTS CAN BE SPACED

(54) Bezeichnung: SPREIZBARES ZWISCHENWIRBELIMPLANTAT

(57) Abstract

The invention concerns an intervertebral implant in the form of a supporting body (1) comprising a central crosspiece (2) and two lateral parts (3, 4) integral with said central crosspiece (2) and forming one single piece therewith. The lateral parts (3, 4) are arranged in two planes (5, 6) extending substantially parallel to each other and separated by the crosspiece (2), and can be applied, as supporting surface, on adjacent vertebral elements. The crosspiece comprises a hollow guide cylinder (7) extending substantially parallel to the lateral parts (3, 4) and between them, and comprises at least one thread (8; 28). A spacing device can be inserted between the lateral parts. The intervertebral implant provides several advantages as follows: the natural lordosis radius of the spine can be specifically restored in a patient, and this angle can be determined before the operation, thereby obtaining for the implant, optimal initial conditions for internal growth; an atraumatic insertion technique is used, since the implant can be delicately screwed and in controlled manner instead of being countersunk; and a simplified operation technique in three stages can be used (also with minimal collapse) by using a guide rod.



### (57) Zusammenfassung

Das Zwischenwirbelimplantat besitzt die Form eines Stützkörpers (1), welcher einen zentralen Steg (2) und einstückig am Steg (2) befestigte Schenkel (3, 4) umfasst. Die Schenkel (3, 4) sind in zwei im wesentlichen parallel zueinander verlaufenden, durch den Steg (2) beabstandeten Ebenen (5, 6) angeordnet, welche als Stützflächen an benachbarte Wirbelkörper anlegbar sind. Der Steg (2) weist einen im wesentlichen parallel zu den Schenkeln (3, 4) und zwischen diesen verlaufenden, hohlen Führungszyylinder (7) mit mindestens einem Gewinde (8; 28) auf. Zwischen den Schenkeln kann eine Spreizvorrichtung eingeführt werden. Das erfindungsgemäße Zwischenwirbelimplantat weist folgende Vorteile auf: der natürliche Lordoseradius der Wirbelsäule kann patientengerecht wiederhergestellt werden und dieser Winkel kann präoperativ bestimmt werden; dadurch ergeben sich für das Implantat optimale Voraussetzungen für dessen Einwachsen; eine atraumatische Insertionstechnik, indem das Implantat sanft und kontrolliert eingeschraubt werden kann, anstelle eines Einschlagvorgangs; und eine vereinfachte (auch minimalinvasive) über einen Führungsstift führbare 3-Schritt-Operationstechnik.

### LEDIGLICH ZUR INFORMATION

Codes zur Identifizierung von PCT-Vertragsstaaten auf den Kopfbögen der Schriften, die internationale Anmeldungen gemäss dem PCT veröffentlichen.

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**Spreizbares Zwischenwirbelimplantat**

Die Erfindung betrifft ein Zwischenwirbelimplantat gemäss dem Oberbegriff des Patentanspruchs 1.

Aus der EP-A1 0 664 994 ist ein solches Zwischenwirbelimplantat bekannt. Die Nachteile dieser Anordnung bestehen darin, dass das Implantat einstückig mit der Spreizvorrichtung ausgebildet ist, so dass es nur als Ganzes in den Zwischenwirbelraum einführbar ist, wobei die Einführung durch Einschlagen des Implantats erfolgen muss. Des weiteren lässt sich das bekannte Zwischenwirbelimplantat nur stufenlos aufspreizen, was dazu führt, dass lediglich eine ungenaue präoperative Planung des Aufspreizwinkels möglich ist.

Hier will die Erfindung Abhilfe schaffen. Der Erfindung liegt das Problem zugrunde, ein Zwischenwirbelimplantat zu schaffen, welches in einer ersten Phase - ohne Spreizvorrichtung - in den Zwischenwirbelraum eingeschraubt werden kann und erst in einer zweiten Phase mittels einer in das Implantat einführbaren Spreizvorrichtung im Zwischenwirbelraum verspreizt wird. Diese Verspreizung soll stufenlos oder kontrolliert erfolgen können, so dass eine präoperative Planung des Aufspreizwinkels ermöglicht wird.

Die Erfindung löst die gestellte Aufgabe mit einem Zwischenwirbelimplantat, welches die Merkmale des Anspruchs 1 aufweist.

Der Führungszyylinder des Implantats ist entweder mit einem Innengewinde oder mit einem Aussengewinde (oder auch mit beidem) versehen. Das Innengewinde erlaubt eine Aufspreizung des Implantats mittels einer Spreizvorrichtung, welche einen Schaft mit einem zum Innengewinde korrespondierenden Gewinde besitzt. Das Aussengewinde auf dem Führungszyylinder erlaubt aber auch eine Aufspreizung des Implantats mittels einer Spreizvorrichtung, welche einen Hohlzylinderteil mit einem zum Aussengewinde korrespondierenden Gewinde besitzt. Die zweite Variante erlaubt wegen der grösseren Durchmesser die Übertragung grösserer Zugkräfte.

Die Ausführung des Führungszyinders mit einem Innen- und einem Aussengewinde hat den zusätzlichen Vorteil, dass eine geführte Operationstechnik möglich ist. Ein im Innengewinde fixierter Führungsstift kann während der gesamten Operation als Führungshilfe benutzt werden, über welche die anderen Instrumente geschoben werden können. Die Operation findet dabei im wesentlichen in drei Schritten statt. Einschrauben des Implantats mit Hilfe einer Gewindegülse, Auffüllung des Implantats mit Knochenspänen, Verspreizung des Implantats im Zwischenwirbelraum gegen die Endplatten. Denkbar ist noch ein zusätzlicher Schritt der darin besteht das Knochenwachstum stimulierende Materialien in flüssiger Form oder als Gel in

den Zwischenwirbelraum einzuspritzen. Zu diesem Zweck können perforierte Einschraub- oder Knochenspan-Insertions-Instrumente verwendet werden.

Eine weitere Ausbildung des Zwischenwirbelimplantats besteht darin, dass die Aussenseiten der Schenkel mit im wesentlich parallel zum Führungszylinder verlaufenden Führungsrippen versehen sind, was die Einführung des Implantats in den Zwischenwirbelraum erleichtert.

Die Schenkel können auch mit Perforationen versehen sein, was das Einwachsen des Knochens begünstigt. Zum gleichen Zweck können auch je zwei Schenkel in den beiden Ebenen des U-förmigen Stützkörpers vorgesehen sein, wobei die Schenkel an den Enden des Stegs angebracht sind, so dass zwischen den beiden Schenkeln in jeder Ebene ein freier Raum besteht, in welchen der Knochen einwachsen kann.

Der Steg des Implantats ist vorzugsweise symmetrisch zu den Schenkeln angeordnet.

Eine bevorzugte Weiterbildung besteht darin, dass die Innenseiten der Schenkel des Implantats mit Rillen versehen sind, welche quer zum Führungszylinder verlaufen. Dies hat den zusätzlichen Vorteil, dass beim Aufspreizen des Zwischenwirbelimplantats das Einstellen eines definierten (präoperative geplanten) Winkels möglich wird.

Eine weitere Ausbildung des Zwischenwirbelimplantats besteht darin, dass seine Schenkel an ihrem vorderen freien Ende eine nach Innen gerichtete Lippe aufweisen; sie verhindert das Herausrutschen der in das Implantat eingefüllten Knochenspäne.

Die durch die Erfindung erreichten Vorteile sind im wesentlichen darin zu sehen, dass dank des erfindungsgemässen Zwischenwirbelimplantats:

- der natürliche Lordoseradius der Wirbelsäule patientengerecht wiederhergestellt werden kann und dass dieser Winkel präoperativ bestimmt werden kann. Dadurch ergeben sich für das Implantat optimale Voraussetzungen für dessen Einwachsen;
- eine atraumatische Insertionstechnik ermöglicht wird, indem das Implantat sanft und kontrolliert eingeschraubt werden kann, anstelle eines Einschlagvorgangs; und
- eine vereinfachte (auch minimalinvasive ) Operationstechnik ermöglicht wird: 3-Schritt-Operationstechnik über einen Führungsstift geführt.

Die Erfindung und Weiterbildungen der Erfindung werden im folgenden anhand der teilweise schematischen Darstellungen mehrerer Ausführungsbeispiele noch näher erläutert.

Es zeigen:

Fig. 1 eine perspektivische Darstellung des erfindungsgemässen Zwischenwirbelimplantats;

Fig. 2 eine Hülse mit Gewinde für das Zwischenwirbelimplantat nach Fig. 1;

Fig. 3 eine perspektivische Darstellung einer Spreizvorrichtung mit Mutter für das Zwischenwirbelimplantat nach Fig. 1;

Fig. 4 eine perspektivische Darstellung einer modifizierten Spreizvorrichtung mit Schraube für das Zwischenwirbelimplantat nach Fig. 1;

Fig. 5 einen Schnitt durch das erfindungsgemäße Zwischenwirbelimplantat mit eingesetzter Hülse mit Gewinde;

Fig. 6 eine perspektivische Ansicht einer modifizierten Hülse mit Gewinde und hohlzylindrischem Schaft;

Fig. 7 einen Schnitt durch das erfindungsgemäße Zwischenwirbelimplantat mit eingesetzter Hülse nach Fig. 6;

Fig. 8 einen Schnitt durch das erfindungsgemäße Zwischenwirbelimplantat mit einem teilweise darin eingeführten Knochenspan-Impaktor zur Auffüllung des Stützkörpers mit Knochenspänen;

Fig. 9 eine perspektivische Teilansicht des Knochenspan-Impaktors nach Fig. 8;

Fig. 10 einen Schnitt durch ein erfindungsgemässes Zwischenwirbelimplantat nach Fig. 1 mit einer eingesetzten Spreizvorrichtung nach Fig. 3, welche mittels eines über den Führungsstift geschobenen Einführungsinstrumentes in den Stützkörper eingeschraubt wird;

Fig. 11 eine perspektivische Teilansicht des Einführungsinstrumentes nach Fig. 10;

Fig. 12 einen Längsschnitt durch ein modifiziertes erfindungsgemässes Zwischenwirbelimplantat (mit verkürztem Führungszylinder) und darin eingeschraubter Spreizvorrichtung nach Fig. 4; und

Fig. 13 eine Vorderansicht des Zwischenwirbelimplantats nach Fig. 12 mit eingeschraubter Spreizvorrichtung.

Das in Fig. 1 dargestellte Zwischenwirbelimplantat besitzt die Form eines Stützkörpers 1, welcher einen zentralen Steg 2 und einstückig am Steg 2 befestigte Schenkel 3,4 umfasst. Die Schenkel 3,4 sind in zwei im wesentlichen parallel zueinander verlaufenden, durch den Steg 2 beabstandete Ebenen 5,6 und symmetrisch zu diesem angeordnet, wobei die Ebenen 5,6 als Stützflächen an benachbarte Wirbelkörper anlegbar sind.

Der Steg 2 weist einen im wesentlichen parallel zu den Schenkeln 3,4 und zwischen diesen verlaufenden, hohlen Führungszyylinder 7 mit einem Innengewinde 8 und einem Aussengewinde 28 auf. Die Innenseiten 25 der Schenkel 3,4 sind mit Rillen 30 versehen, welche quer zum Führungszyylinder 7 verlaufen. Die Aussenseiten 24 der Schenkel 3,4 sind mit im wesentlich parallel zum Führungszyylinder 7 verlaufenden Führungsrippen 12 versehen. Die Schenkel 3,4 sind im übrigen mit Perforationen 22 versehen und besitzen an ihrem vorderen freien Ende eine nach Innen gerichtete Lippe 29.

Je zwei Schenkel 3;4 sind in den beiden Ebenen 5,6 des U-förmigen Stützkörpers 1 vorgesehen, wobei die Schenkel 3,4 an den Enden des Stegs 2 angebracht sind, so dass zwischen den beiden Schenkeln in jeder Ebene 5,6 ein freier Raum 23 besteht.

In Fig. 2 ist eine Hülse 9 mit Aussengewinde 10, Hohlraum 13 und Sechskantvertiefung 34 dargestellt, welche auf den Führungszyylinder 7 des Stützkörpers 1 geschoben werden kann. Sie hat vorzugsweise einen Durchmesser, der leicht grösser ist als die Höhe des Stützkörpers 1 (Abstand der Ebenen 5 und 6). Die in den Stützkörper 1 eingeführte Hülse 9 kann mittels eines geeigneten, in die Sechskantvertiefung 34 eingeführten Instrumentes um den Führungszyylinder 7 rotiert werden und dient zur Einführung des Stützkörpers 1 in den Zwischenwirbelraum. Da die Hülse 9 etwas über die Aussenseiten 24 der Schenkel 3,4 hervorragt, greift ein Teil ihres Aussengewindes 10 in das Knochenmaterial der benachbarten Wirbelkörper, so dass damit der

Stützkörpers 1 ohne Mühe in den Zwischenwirbelraum eingedreht werden kann. Nach erfolgter Einführung des Stützkörpers 1 in den Zwischenwirbelraum kann dann die Hülse 9 ebenso leicht wieder über den Führungszyylinder 7 zurück- und ausgeschraubt werden.

In den Fig. 3 und 4 sind zwei Varianten für eine, den Stützkörper 1 expandierende Spreizvorrichtung 11 dargestellt, welche beide einen identischen Spreizkörper 18 umfassen. Der Spreizkörper 18 hat die Form eines Quaders mit einer zentralen Bohrung 19, an welchem seitlich zwei Nocken 21 angebracht sind, welche zwischen die Schenkel 3,4 einföhrbar sind. Der Spreizkörper 18 weist zudem zwei Seitenschlitze 55 auf, welche der Erfassung und Handhabung des Spreizkörpers 18 dienen.

Die erste - in Fig. 3 dargestellte - Variante der Spreizvorrichtung 11 umfasst im weiteren eine hohlzylinderförmige Mutter 26 mit Innengewinde 27, welche mit dem Aussengewinde 28 des Führungszyinders 7 korrespondiert. Die Bohrung 19 ist derart ausgestaltet, dass die Mutter 26 bis zum Anschlag 45 darin einföhrbar ist.

Die zweite - in Fig. 4 dargestellte - Variante der Spreizvorrichtung 11 umfasst (statt der Mutter 26) eine Schraube 14 mit einem, einen Innensechskant 44 aufweisenden Kopf 16 und einem, ein Aussengewinde 15 tragenden Schaft 20. Das Aussengewinde 15 korrespondiert dabei mit dem Innengewinde 8 des Führungszyinders 7. Der Kopf 16 der Schraube 14 kommt - analog zur Mutter 26 (Fig. 3) - am Anschlag 45 im Inneren der zentralen Bohrung 19 zum Anliegen.

Bei Verwendung der zweiten, in Fig. 4 dargestellten Variante der Spreizvorrichtung 11 muss der Führungszylinder 7 verkürzt werden, so wie dies in Fig. 12 dargestellt ist, d.h. etwa halb so lang sein, wie in Fig. 1 dargestellt.

Anhand der Figuren 5 - 13 wird nun die Operationstechnik des erfindungsgemässen Zwischenwirbelimplantats näher beschrieben.

Nach erfolgter Entfernung von genügend Bandscheibenmaterial wird der U-förmige Stützkörper 1 zwischen die betroffenen Wirbel eingeführt. Zu diesem Zweck wird - wie in Fig. 5 dargestellt - über dessen Führungszylinder 7 die Hülse 9 mit Aussengewinde 10 aufgeshoben. Der U-förmige Stützkörper 1 mit der aufgeshobenen Hülse 9 wird leicht in den aufbereiteten Zwischenwirbelraum eingeklopft, bis der erste Gang des Aussengewindes 10 in das Knochenmaterial greift. Dann wird der U-förmige Stützkörper 1 durch weiteres Eindrehen der Hülse 9 auf die gewünschte Tiefe in den Zwischenwirbelraum eingeschraubt. Das Eindrehen der Hülse 9 kann dabei durch ein in den Innensechskant 34 eingeführtes Eindrehinstrument erfolgen.

Bei einer in den Fig. 6 und 7 dargestellten Variante ist die Hülse 9 mit Aussengewinde 10 an einem hohlzylindrischen Schaft 46 befestigt und stellt einen Teil eines Einführungsinstrumentariums dar. Um das Einführungsinstrumentarium axial besser führen zu können, kann vorgängig ein an seinem vorderen Ende mit einem Aussengewinde 32 (Fig. 10) versehener Führungsstift

31 (Fig. 7) in das Innengewinde 8 des Führungszyllinders 7 des Stützkörpers 1 eingeschraubt werden, wo er während der gesamten Operationszeit verbleiben kann. Die Hülse 9 gemäss Fig. 6 kann dann einfach mit ihrem hohlzylindrischen Schaft 46 über den Führungsstift 31 auf den Führungszyllinder 7 geschoben und dort rotiert werden.

Die auf den Aussenseiten 24 der Schenkel 3,4 des Stützkörpers 1 verlaufenden Führungsrippen 12 verhindern, dass der Stützkörper 1 während des Einschraubvorgangs von der gewünschten Richtung abweicht.

Die Hülse 9 wird nach Abschluss des Einschraubvorgangs wieder aus dem Stützkörper 1 herausgeschraubt. Da zwischen der Oberfläche des Führungszyllinders 7 und der Innenfläche der Hülse 9 praktisch keine Reibung besteht, bleibt der Stützkörper 1 während des Herausschraubens der Hülse 9 unverändert an seinem Ort.

Nun schliesst sich fakultativ - wie in Fig. 8 dargestellt - die Einführung von Knochenspänen 47 in den freien Raum 23 des Stützkörpers 1 an. Zu diesem Zweck werden - mittels eines Knochenspan-Impaktors 33 - Knochenspäne 47 in den freien Raum 23 eingeführt und komprimiert. Der in Fig. 8 dargestellte Knochenspan-Impaktor 33 besteht aus einem flachen Grundkörper 48, der - wie in Fig. 8 gezeigt - teilweise zwischen die

Schenkel 3,4 einführbar und an einem hohlzylindrischen Schaft 49 befestigt ist. Auch der Knochenspan-Impaktor 33 kann über den Führungsstift 31 axial geführt werden.

Schliesslich erfolgt - wie in Fig. 10 dargestellt - die Einführung einer Spreizvorrichtung 11 zwischen die Ebenen 5,6 und den darin angeordneten Schenkeln 3,4 des Stützkörpers 1. Die Spreizvorrichtung 11 gemäss Fig. 3 wird nun im zusammengesetzten Zustand (d.h. mit der in der Bohrung 19 eingesetzten Mutter 26), mittels des Einführungsinstrumentes 40, mit ihren beiden Nocken 21 zwischen die Schenkel 3,4 eingeführt.

Das vordere Ende des Einführungsinstrumentes 40 ist im Detail in Fig. 11 dargestellt. Die rotierbare Hülse 41 weist an ihrem vorderen Ende vier Antriebsnocken 50 für die Mutter 26 auf; zu diesem Zweck sind in der Mutter vier korrespondierende Längsnuten 56 eingelassen, so dass sich die Mutter 26 damit drehen lässt. Die rotierbare Hülse 41 ist in der Haltehülse 52 mit geriffeltem Ring 53 gelagert und weist an ihrem vorderen Ende zwei Haltestifte 54 auf, welche in die Seitenschlitze 55 (Fig. 3) der Nocken 21 einführbar sind, um damit den Spreizkörper 18 zu halten.

Bei Verwendung einer Spreizvorrichtung 11 nach Fig. 4, welche neben dem identischen Spreizkörper 18 eine Schraube 14 (statt der Mutter 26) umfasst, wird - wie in den Fig. 12 und 13 dargestellt - der Schaft 20 der Schraube 14 mit seinem Gewinde

15 in das Innengewinde 8 des hohlen Führungszyinders 7 eingeführt. Das Einschrauben der Schraube 14 in den Führungszyylinder 7 bewirkt - wegen des Anschlags 45 des Schraubenkopfes 16 in der Bohrung 19 - eine axiale Verschiebung des Spreizkörpers 18 in Richtung des Führungszyinders 7, wobei die daran befestigten Nocken 21 in die Schenkel 3,4 eindringen und diese Aufspreizen. Durch kontinuierliches Eindrehen der Schraube 14 können die Schenkel 3,4 soweit aufgespreizt werden, dass ihre Ebenen 5,6 einen Winkel  $\alpha$  von bis zu 10 - 12° einschliessen. Das Eindrehen der Schraube 14 kann mittels eines in die Sechskantöffnung 44 im Kopf 16 eingeführten Instrumentes erfolgen.

Patentansprüche

1. Zwischenwirbelimplantat in Form eines Stützkörpers (1), welcher einen zentralen Steg (2) und einstückig am Steg (2) befestigte Schenkel (3,4) umfasst, wobei die Schenkel (3,4) in zwei im wesentlichen parallel zueinander verlaufenden, durch den Steg (2) beabstandeten Ebenen (5,6) angeordnet sind, welche als Stützflächen an benachbarte Wirbelkörper anlegbar sind,

**dadurch gekennzeichnet, dass**

der Steg (2) einen im wesentlichen parallel zu den Schenkeln (3,4) und zwischen diesen verlaufenden, hohlen Führungszyliner (7) mit mindestens einem Gewinde (8;28) aufweist.

2. Zwischenwirbelimplantat nach Anspruch 1, dadurch gekennzeichnet, dass der hohle Führungszyliner (7) entweder ein Innengewinde (8) oder ein Aussengewinde (28) besitzt.

3. Zwischenwirbelimplantat nach Anspruch 1, dadurch gekennzeichnet, dass der hohle Führungszyliner (7) ein Innengewinde (8) und ein Aussengewinde (28) besitzt.

4. Zwischenwirbelimplantat nach einem der Ansprüche 1 bis 3, dadurch gekennzeichnet, dass die Innenseiten (25) der Schenkel (3,4) mit Rillen (30) versehen sind, welche quer zum Führungszyliner (7) verlaufen.

5. Zwischenwirbelimplantat nach einem der Ansprüche 1 bis 4, dadurch gekennzeichnet, dass die Aussenseiten (24) der Schenkel (3,4) mit im wesentlich parallel zum Führungszyylinder (7) verlaufenden Führungsrippen (12) versehen sind.

6. Zwischenwirbelimplantat nach einem der Ansprüche 1 bis 4, dadurch gekennzeichnet, dass die Aussenseiten (24) der Schenkel (3,4) mit im wesentlich parallel zum Führungszyylinder (7) verlaufenden Querrillen, insbesondere einem Fischgrätenprofil oder Sägezahnprofil versehen sind.

7. Zwischenwirbelimplantat nach einem der Ansprüche 1 bis 6, dadurch gekennzeichnet, dass die Schenkel (3,4) mit Perforationen (22) versehen sind.

8. Zwischenwirbelimplantat nach einem der Ansprüche 1 bis 7, dadurch gekennzeichnet, dass je zwei Schenkel (3;4) in den beiden Ebenen (5,6) des U-förmigen Stützkörpers (1) vorgesehen sind, wobei die Schenkel (3,4) an den Enden des Stegs (2) angebracht sind, so dass zwischen den beiden Schenkeln (3,4) in jeder Ebene (5,6) ein freier Raum (23) besteht.

9. Zwischenwirbelimplantat nach einem der Ansprüche 1 bis 8, dadurch gekennzeichnet, dass der Steg (2) symmetrisch zu den Schenkeln (3,4) angeordnet ist.

10. Zwischenwirbelimplantat nach einem der Ansprüche 1 bis 9, dadurch gekennzeichnet, dass die Schenkel (3;4) an ihrem vorderen freien Ende eine nach Innen gerichtete Lippe (29) aufweisen.

11. Zwischenwirbelimplantat nach einem der Ansprüche 1 bis 10, dadurch gekennzeichnet, dass es weiter einen im Innengewinde (8) des Führungszyinders (7) fixierbaren Führungsstift (31) umfasst.

12. Zwischenwirbelimplantat nach einem der Ansprüche 1 bis 11, dadurch gekennzeichnet, dass es weiter eine auf den Führungszyylinder (7) aufschiebbare Hülse (9) mit Aussengewindeteil (10) umfasst.

13. Zwischenwirbelimplantat nach einem der Ansprüche 1 bis 12, dadurch gekennzeichnet, dass es weiter einen zwischen die Ebenen (5,6) und den darin angeordneten Schenkeln (3,4) einführbare Spreizvorrichtung (11) für die Schenkel (3,4) umfasst, wobei die Spreizvorrichtung eine Schraube (14) mit Schaft (20) mit einem zum Innengewinde (8) korrespondierenden Gewinde (15) aufweist.

14. Zwischenwirbelimplantat nach einem der Ansprüche 1 bis 12, dadurch gekennzeichnet, dass es weiter einen zwischen die Ebenen (5,6) und den darin angeordneten Schenkeln (3,4) einführbare Spreizvorrichtung (11) für die Schenkel (3,4) umfasst, wobei die

Spreizvorrichtung eine hohlzylindrische Mutter (26) mit einem zum Aussengewinde (28) korrespondierenden Innengewinde (27) aufweist.

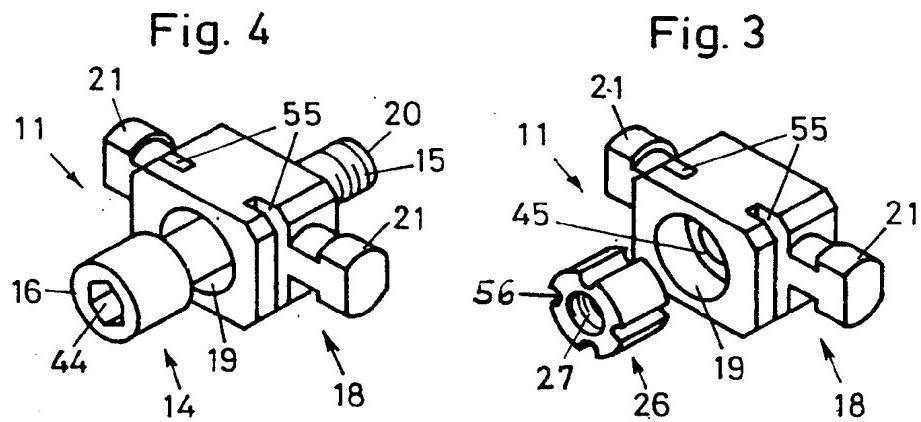
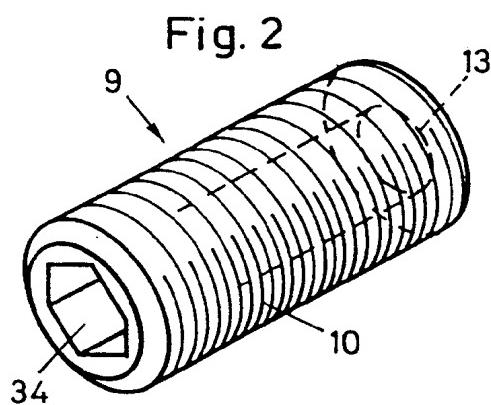
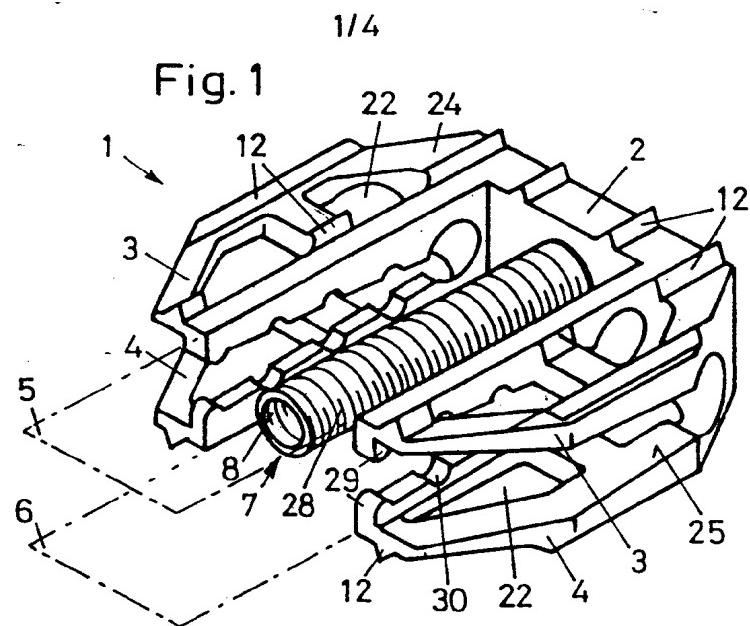


Fig. 5

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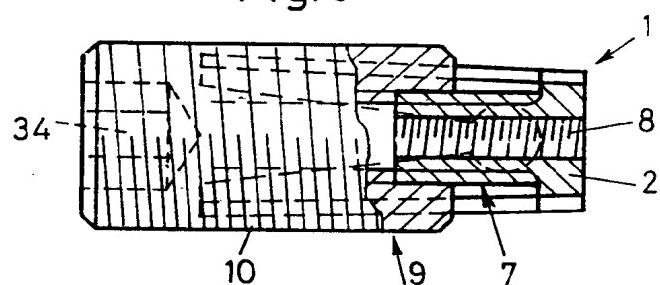


Fig. 6

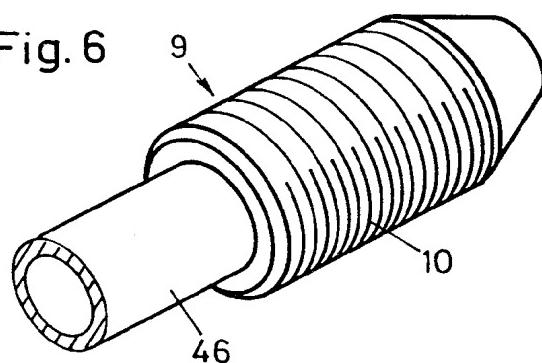


Fig. 7

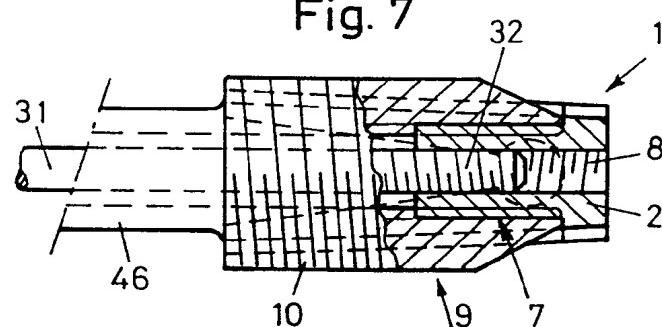
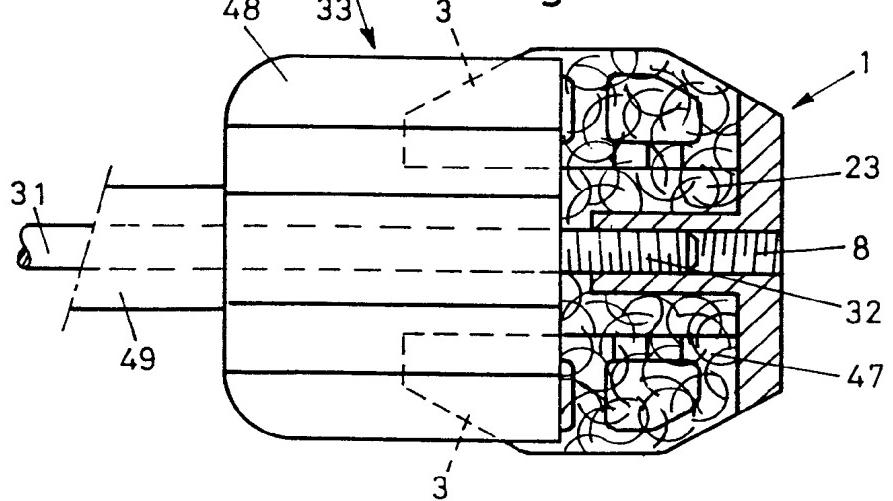


Fig. 8



3/4

Fig. 9

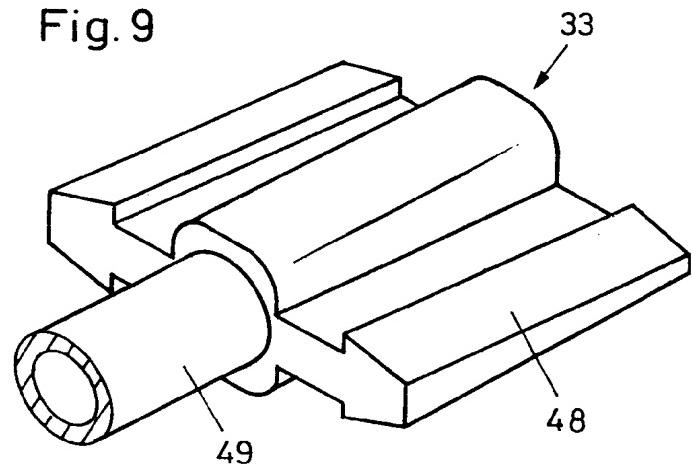


Fig.11

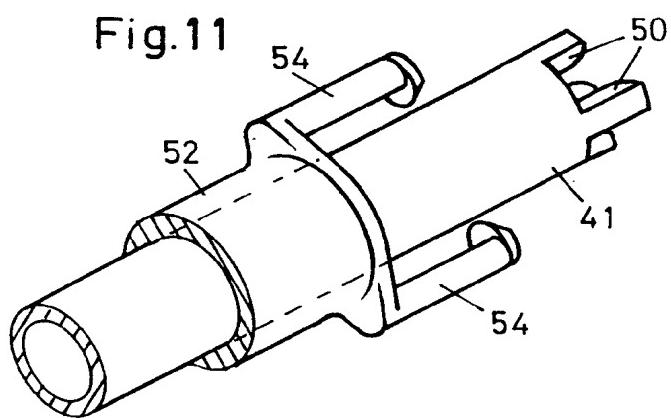


Fig. 12

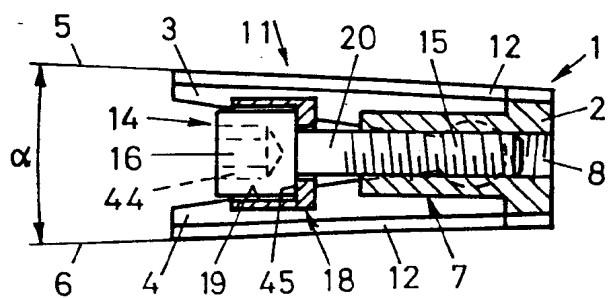
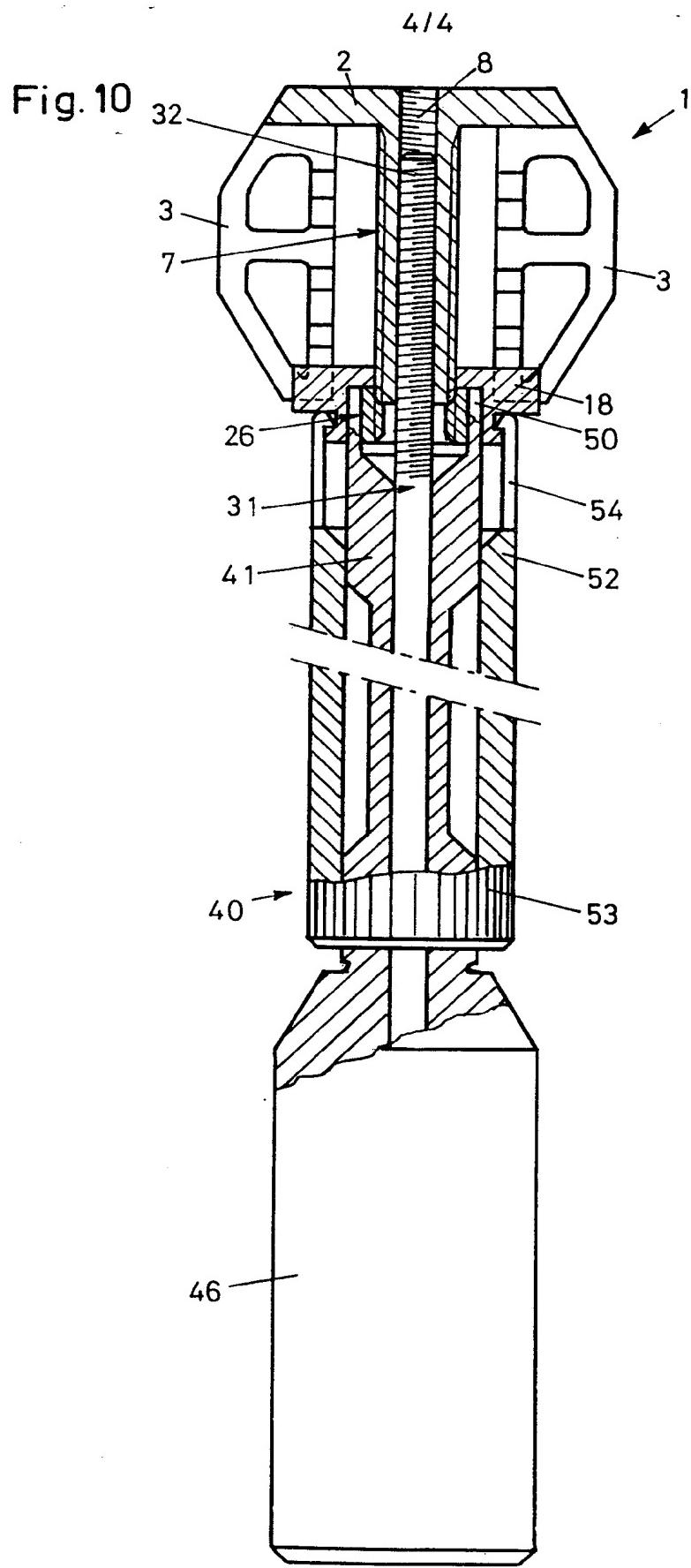


Fig. 13



# INTERNATIONAL SEARCH REPORT

In International Application No  
PCT/CH 97/00293

**A. CLASSIFICATION OF SUBJECT MATTER**

IPC 6 A61F2/44

According to International Patent Classification(IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)  
IPC 6 A61F

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Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 664 994 A (BIOMAT) 2 August 1995 see abstract; figures -----	1,13
A	US 5 653 763 A (ERRICO ET AL.) 5 August 1997 see abstract; figures -----	1,13
A	DE 44 16 605 C (AESCULAP) 8 June 1995 see abstract; figures -----	1,13

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1

Date of the actual completion of the international search

Date of mailing of the international search report

22 April 1998

06/05/1998

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# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/CH 97/00293

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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US 5653763 A	05-08-97	US 5714145 A	03-02-98
DE 4416605 C	08-06-95	DE 9407806 U	14-07-94

# INTERNATIONALER RECHERCHENBERICHT

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PCT/CH 97/00293

**A. KLASIFIZIERUNG DES ANMELDUNGSGEGENSTANDES**  
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**C. ALS WESENTLICH ANGESEHENE UNTERLAGEN**

Kategorie*	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
A	EP 0 664 994 A (BIOMAT) 2.August 1995 siehe Zusammenfassung; Abbildungen ----	1,13
A	US 5 653 763 A (ERRICO ET AL.) 5.August 1997 siehe Zusammenfassung; Abbildungen ----	1,13
A	DE 44 16 605 C (AESCULAP) 8.Juni 1995 siehe Zusammenfassung; Abbildungen -----	1,13

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Bevollmächtigter Bediensteter

Hagberg, A

**INTERNATIONALER RECHERCHENBERICHT**

Angaben zu Veröffentlichungen, die zur selben Patentfamilie gehören

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PCT/CH 97/00293

Im Recherchenbericht angeführtes Patentdokument	Datum der Veröffentlichung	Mitglied(er) der Patentfamilie		Datum der Veröffentlichung
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